

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION.

GILEAD SCIENCES, INC.,) CV-13-4057-BLF
)
PLAINTIFF,) SAN JOSE, CALIFORNIA
)
VS.) APRIL 3, 2015
)
MERCK & CO, INC., ET AL,) PAGES 1-96
)
DEFENDANT.)

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE BETH LABSON FREEMAN
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: FISH & RICHARDSON PC
BY: DOUGLAS MCCANN
ELIZABETH FLANAGAN
222 DELAWARE AVE, 17TH FL
WILMINGTON, DE 19801

FOR THE DEFENDANT: HUGHES HUBBARD & REED, LLP
BY: STEPHEN RABINOWITZ
WANDA FRENCH BROWN
LAURA MILLER
ONE BATTERY PARK PLAZA
NEW YORK, NY 10004

APPEARANCES CONTINUED ON THE NEXT PAGE

OFFICIAL COURT REPORTER: SUMMER FISHER, CSR, CRR
CERTIFICATE NUMBER 13185

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

1 FOR THE PLAINTIFF: FISH & RICHARDSON, PC
2 BY: JOHN FARRELL
RACHEL SANCHEZ
3 500 ARGUELLO STREET, STE 500
REDWOOD CITY, CA 94063

4 ALSO PRESENT: JAMIE LYNCH
GILEAD KATHERINE RICE

5
6 ALSO PRESENT: GERARD DEVLIN
MERCK

7
8 ALSO PRESENT: CLIFF FORD
ISIS JEFFREY TUNG

9
10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

1 SAN JOSE, CALIFORNIA

APRIL 3, 2015

2 P R O C E E D I N G S

3 (WHEREUPON, COURT CONVENED AND THE FOLLOWING PROCEEDINGS
4 WERE HELD:)

5 THE COURT: ALL RIGHT. LET'S CALL OUR CASE.

6 THE CLERK: CALLING CASE 13-4057. GILEAD SCIENCES
7 VERSUS MERCK, ET AL.

8 COUNSEL, PLEASE COME FORWARD AND STATE YOUR APPEARANCES.

9 MR. MCCANN: GOOD MORNING, YOUR HONOR.

10 FOR THE PLAINTIFF, DOUG MCCANN FROM FISH RICHARDSON.

11 WITH ME AT COUNSEL TABLE IS ELIZABETH FLANAGAN, AND YOU
12 MET LAST WEEK MS. SANCHEZ AND MR. FARRELL.

13 AND YOUR HONOR, I HAVE QUITE A GALLERY HERE IN THE BACK.

14 THE COURT: I CAN SEE THAT.

15 MR. MCCANN: I DID WANT TO SPECIFICALLY INTRODUCE
16 LORIE ANN MORGAN WHO IS THE VICE PRESIDENT OF INTELLECTUAL
17 PROPERTY. YOU ALSO MET MS. LYNCH AND MS. RICE, ALSO FROM THE
18 GILEAD LEGAL DEPARTMENT.

19 THE COURT: YES. GOOD MORNING.

20 MR. MCCANN: MY OTHER COLLEAGUES, YOUR HONOR, ARE
21 PATENT PROSECUTORS FROM GILEAD WHO HAVE NEVER SEEN A MARKMAN
22 HEARING BEFORE. SO THEY THOUGHT THEY WOULD COME THIS MORNING
23 AND SEE HOW I DO AND ALSO WHAT A MARKMAN HEARING IS ALL ABOUT.

24 THE COURT: THEY SEE WHAT HAPPENS TO THEIR FINE
25 PRODUCT WHEN THEY TURN IT OVER TO YOU.

1 MR. MCCANN: WE WILL FIND OUT, YOUR HONOR.

2 THE COURT: ALL RIGHT. THANK YOU.

3 GO AHEAD.

4 MR. RABINOWITZ: GOOD MORNING, YOUR HONOR.

5 STEPHEN RABINOWITZ FROM HUGHES HUBBARD & REED FOR THE
6 DEFENDANTS MERCK AND ISIS PHARMACEUTICALS.

7 THE COURT: GOOD MORNING, MR. RABINOWITZ.

8 MR. RABINOWITZ: WITH ME AT COUNSEL TABLE ARE LAURA
9 MILLER AND WANDA FRENCH-BROWN.

10 THE COURT: GOOD MORNING.

11 AND I'M GOING TO STOP AGAIN, I'M NOT GETTING
12 ANY REALTIME.

13 (OFF THE RECORD DISCUSSION.)

14 THE COURT: ALL RIGHT.

15 MR. RABINOWITZ: YOUR HONOR, I JUST WANTED TO MENTION
16 THAT WE ARE ACCOMPANIED HERE BY GERARD DEVLIN FROM MERCK, AND
17 BY CLIFF FORD AND JEFFREY TUNG FROM ISIS.

18 THE COURT: GOOD MORNING. ALL RIGHT. I DO
19 APPRECIATE EVERYONE BEING HERE.

20 TODAY WE ARE GOING TO FOCUS ON THE ONE TERM
21 "ADMINISTERING." AND IN MERCK'S VIEW IT'S SIMPLE, IT'S DEFINED
22 IN THE PATENT AND WE SHOULD BE DONE, AND WE HAVE ABOUT A
23 FIVE-MINUTE HEARING.

24 AND SO BEFORE YOU START YOUR PRESENTATIONS, AND I'M SURE
25 YOU ARE PLANNING TO COVER THIS, I WANTED TO IDENTIFY SOME

1 CONCERNS ON MY MIND SO THAT WE DON'T HAVE TO GO BACK OVER THESE
2 THINGS.

3 AND I'M GOING -- I'M PRESUMING THAT THESE ARE WELL
4 EMBEDDED INTO YOUR PRESENTATIONS, BUT IN THE -- I JUST WANTED
5 TO HIGHLIGHT IT SO YOU KNOW IT'S MY CONCERN.

6 IT FEELS TO ME A LITTLE BIT LIKE THIS IS KABUKI THEATRE
7 THAT WE ARE TALKING ABOUT ONE WORD BUT WE ARE REALLY TALKING
8 ABOUT SOMETHING ENTIRELY DIFFERENT.

9 AND IT DOES APPEAR THAT IT IS NOT THE TERM
10 "ADMINISTERING" THAT ANYONE IS AT ALL CONCERNED WITH. THE
11 CONCERN IS THE DEFINITION OF A PRODRUG OF A COMPOUND OF THE
12 INVENTION. AND IT IS IN BOTH OF YOUR BRIEFS, IT'S NOT THAT YOU
13 DIDN'T ADDRESS IT HEAD ON, BUT IN THE MANY PAGES OF BRIEFING,
14 IT IS A FEW LINES IN EACH OF YOUR BRIEFS.

15 GILEAD DIRECTLY STATES THAT THE COURT HAS THE AUTHORITY
16 TO CONSTRUE WHAT THE COURT HAS CALLED DERIVATIVE TERMS. AND
17 MERCK IN ITS CLOSING BRIEF DEFINES PRODRUG OF A COMPOUND OF THE
18 INVENTION BY DIRECTLY SAYING THAT THIS TERM MEANS AND GIVING A
19 DEFINITION.

20 AND FRANKLY, I THINK THAT'S WHAT THIS ENTIRE HEARING IS
21 ABOUT, OR AT LEAST THAT. AND I DON'T KNOW WHETHER THIS IS THE
22 TIME AND PLACE TO BE ADDRESSING THAT ISSUE. BUT AT THE END --
23 BY THE END OF THE HEARING I DO WANT EACH OF YOU TO BE ABLE TO
24 ANSWER THE QUESTION FOR ME THAT IF I WERE TO ACCEPT MERCK'S
25 CONSTRUCTION, WOULD THAT PRECLUDE FURTHER ARGUMENT AND

1 DETERMINATION OF THE PHRASES THAT GILEAD HAS ADDED TO THE
2 DEFINITION IN ITS CONSTRUCTION.

3 AND YOU KNOW, I KNOW THAT GILEAD SUGGESTS IN ITS PAPERS
4 THAT THE BROAD CONSTRUCTION ARGUED BY MERCK COULD INVITE THE
5 INVALIDITY ARGUMENT, THAT'S NOT BEFORE ME TODAY. I DON'T PLAN
6 TO TAKE THAT ON, BUT I'M JUST REALLY CONCERNED THAT YOU'RE
7 TALKING ABOUT ONE THING AND REALLY WANTING A DECISION ON
8 SOMETHING ELSE.

9 SO THAT BEING SAID, I'M READY NOW TO LEAVE IT IN YOUR
10 HANDS TO INFORM ME OF THE VARIOUS FACTORS I SHOULD CONSIDER IN
11 CONSTRUING THE TERM ADMINISTERING.

12 SO MR. RABINOWITZ, I GUESS YOU GET TO GO FIRST, YOUR
13 COMPANY OWNS THIS PATENT.

14 MR. RABINOWITZ: THANK YOU, YOUR HONOR.

15 SO YOUR HONOR, PERHAPS I CAN ALLUDE TO WHY I THINK THE
16 ARGUMENT IS COMING UP IN THE GUISE OF CONSTRUING THE TERM
17 ADMINISTERING.

18 AND THAT IS BECAUSE THERE'S A STRONG PRINCIPLE
19 ESTABLISHED IN THE FEDERAL CIRCUIT PRECEDENT THAT ONE MAY NOT
20 IMPORT EXTRANEOUS LIMITATIONS INTO A CLAIM BY WAY OF
21 CONSTRUCTION. THE ONLY LEGITIMATE WAY OF DETERMINING THE SCOPE
22 OF A CLAIM IS TO DETERMINE THE MEANING OF WORDS THAT ARE
23 ACTUALLY PRESENT IN THE CLAIM. THERE HAS TO BE A HOOK FOR A
24 CLAIM CONSTRUCTION EXERCISE.

25 AND THE ONLY POSSIBLE WORD IN CLAIM ONE OF THE '499

1 PATENT THAT COULD BE CONSTRUED IN THE WAY THAT GILEAD WOULD
2 LIKE IT CONSTRUED TO ADD THOSE LIMITATIONS TO THE CLAIM IS
3 ADMINISTERING. AND IF THOSE LIMITATIONS DON'T FIT AS A
4 CONSTRUCTION OF THAT WORD, THEY ARE EXTRANEIOUS AND MAY NOT BE
5 INCLUDED INTO THE CLAIMS.

6 THE COURT: AND SO YOU ARGUE IN YOUR BRIEF THAT THE
7 PATENTEE DEFINED THIS TERM AND THAT UNDER PHILLIPS I SHOULD
8 SIMPLY ACCEPT THIS DEFINITION. AND IF I WERE TO DO THAT, IN MY
9 VIEW, IF I HAVE A DEFINITION, THE WORD "ADMINISTERING"
10 ESSENTIALLY IS A PLACEHOLDER FOR THE MULTI-WORD PHRASE.

11 AND SO I WOULD IMPORT THAT PHRASE OR SENTENCE OR TWO
12 SENTENCES INTO THE CLAIM, AND THEN I WOULD CONSTRUE ALL OF
13 THOSE WORDS.

14 SO THAT'S WHERE I HAVE TROUBLE.

15 MR. RABINOWITZ: YES.

16 WELL, I THINK THAT THE CONSTRUCTION OF "ADMINISTERING"
17 DOES RAISE THE ISSUE THAT GILEAD WANTS TO BRING BEFORE THE
18 COURT.

19 AND WE THINK THE COURT SHOULD REJECT THE LIMITATIONS THAT
20 GILEAD WOULD SEEK TO IMPORT FOR THE REASON THAT THEY ARE NOT A
21 PROPER CONSTRUCTION OF THE WORD "ADMINISTERING", UNLESS THERE
22 ARE A PROPER BYPRODUCT OF CONSTRUING THE WORD "ADMINISTERING",
23 THEY MAY NOT BE IMPORTED INTO THE CLAIM UNDER THE PRINCIPLE
24 THAT EXTRANEIOUS LIMITATIONS MAY NOT BE IMPORTED BY
25 CONSTRUCTION.

1 THE COURT: SO YOU AGREED WITH ME A MINUTE AGO AND
2 NOW YOU'RE NOT AGREEING WITH ME.

3 MR. RABINOWITZ: I'M AGREEING PROCEDURALLY THAT THE
4 COURT HAS THE AUTHORITY TO MAKE THAT DECISION, AND I'M SAYING
5 SUBSTANTIVELY THE COURT SHOULD REJECT THE LIMITATIONS THAT
6 GILEAD ARE PROPOSING TO BE IMPORTED INTO THE CLAIMS.

7 THE COURT: I APPRECIATE THAT.

8 MR. RABINOWITZ: BECAUSE THEY DO NOT FIT AS A
9 DEFINITION OF "ADMINISTERING", THE WAY THE SPECIFICATION
10 DEFINES ADMINISTERING. AND I'M GOING TO EXPLAIN WHY.

11 IT REQUIRES SOME BACKGROUND KNOWLEDGE OF SCIENTIFIC
12 PRINCIPLES AND CONSIDERATION OF WHAT THE PATENT SAYS AND WHAT
13 THE INVENTION IS AND SO FORTH.

14 THE COURT: NOW I SAID I WAS GOING TO LISTEN AND THEN
15 I DIDN'T, SO I'M SORRY. I NOW WANT TO HEAR YOUR PRESENTATION
16 AND THEN I'M PROBABLY GOING TO COME BACK TO THIS. BUT MAYBE I
17 WILL HOPEFULLY BE BETTER EDUCATED AT THE BACK END OF YOUR
18 PRESENTATION AND BE ABLE TO HAVE A MORE PRODUCTIVE SET OF
19 QUESTIONS FOR YOU.

20 MR. RABINOWITZ: YOUR HONOR, I'M DELIGHTED TO ANSWER
21 YOUR HONOR'S QUESTIONS AT ANY TIME, AND I WELCOME THEM DURING
22 THE COURSE OF THE PRESENTATION, IT WON'T PUT ME OFF.

23 THE COURT: THANK YOU SO MUCH.

24 ALL RIGHT. GO AHEAD.

25 MR. RABINOWITZ: SO YOUR HONOR, I WANTED TO FOCUS ON

1 SOME CLAIM TERMS THAT ARE NOT IN DISPUTE BUT ARE NEVERTHELESS
2 RELEVANT TO OUR DISCUSSION.

3 AND THESE ARE THE TERMS COMPOUND, WHICH WAS ORIGINALLY
4 DISPUTED BUT WHICH GILEAD NOW AGREES MEANS A SUBSTANCE THAT
5 CONSISTS OF TWO OR MORE CHEMICAL ELEMENTS IN UNION.

6 AND I THINK THIS IS RELEVANT BECAUSE THE ARGUMENTS THAT
7 WERE MADE IN SUPPORT OF THE NOW DISCARDED NARROWING
8 CONSTRUCTION OF COMPOUND ARE SIMILAR, THEY BEAR A RESEMBLANCE
9 TO THE ARGUMENTS THAT ARE BEING MADE IN FAVOR OF THE ADDITIONAL
10 LIMITATIONS THAT ARE BEING URGED BY GILEAD FOR ADMINISTERING.

11 AND "IN COMBINATION WITH", AND THIS RELATES TO ONE OF THE
12 ARGUMENTS THAT GILEAD IS MAKING, BUT THE TERM "IN COMBINATION
13 WITH" DOESN'T HAVE ITS ORDINARY MEANING IN THE PATENT, THERE'S
14 A SPECIAL DEFINITION IN THE SPECIFICATION AND WE BROTH AGREE
15 WITH IT.

16 SO "IN COMBINATION WITH" IS SPECIFICALLY DEFINED IN THE
17 SPECIFICATION AND IT'S STIPULATED TO MEAN, "TOGETHER WITH."
18 THIS IS CLAIM 2 OF THE '499 PATENT WHICH SAYS THAT THE COMPOUND
19 OF STRUCTURAL FORMULA 3 OR PHARMACEUTICALLY ACCEPTABLE SALT OR
20 ESTER DERIVATIVES THEREOF IS IN COMBINATION WITH, THE
21 THERAPEUTIC ADVANCE OF ANOTHER AGENT, AND THEN IT SPECIFIES A
22 LIST FROM WHICH THE OTHER AGENT CAN BE DERIVED.

23 AND IN COMBINATION WITH DOESN'T MEAN WHAT YOU MIGHT THINK
24 IT MEANS IF YOU SIMPLY READ THAT LANGUAGE, IT SPECIFICALLY
25 MEANS TOGETHER WITH, WHETHER GIVEN SEPARATELY AT DIFFERENT

1 TIMES DURING THE COURSE OF THERAPY.

2 IN OTHER WORDS, THE PATIENT HAS HEPATITIS C, AS YOU HEARD
3 FROM GILEAD'S COUNSEL LAST WEEK, THE COURSE OF THERAPY LASTS
4 FOR MONTHS. AND THE PATIENT IS CONCURRENTLY BEING TREATED WITH
5 TWO AGENTS, GIVEN SEPARATE -- IN THE FIRST PART OF THAT
6 DEFINITION, GIVEN SEPARATELY AT DIFFERENT TIMES. OR
7 CONCURRENTLY, AND THEN IT CAN BE IN DIVIDE DOSES. IN OTHER
8 WORDS, ONE PILL IN ANOTHER PILL OR ONE PILL IN AN INJECTION OR
9 IN SINGLE COMBINATION FORMS.

10 THE COURT: SO AT ANY TIME DURING THE COURSE OF THE
11 TREATMENT.

12 MR. RABINOWITZ: THAT'S RIGHT.

13 THE PATIENT IS BEING TREATED WITH TWO AGENTS, MAYBE ONE
14 IN THE MORNING, ONE AT NIGHT, OR MAYBE BOTH IN THE MORNING IN
15 SEPARATE MEDICATIONS OR PERHAPS A SINGLE, A FIXED DOSE
16 MEDICATION.

17 THE COURT: IT COULD BE IN ONE WEEK VERSUS ANOTHER
18 WEEK TOO.

19 MR. RABINOWITZ: YES. DURING THE COURSE OF THERAPY.
20 AND THIS IS A COURSE OF THERAPY THAT LASTS MONTHS LONG.

21 THE COURT: YES, OKAY.

22 MR. RABINOWITZ: SO THE TERM THAT IS IN DISPUTE IS
23 "ADMINISTERING." AND HERE ARE THE TWO PROPOSED DEFINITIONS:

24 MERCK'S PROPOSED DEFINITION IS SIMPLY WHAT THE
25 SPECIFICATION SAYS, "PROVIDING A COMPOUND OF THE INVENTION OR A

1 PRODRUG OF A COMPOUND OF THE INVENTION TO THE INDIVIDUAL IN
2 NEED."

3 THE COURT: WHICH IS NOT IN DISPUTE. BOTH OF YOU
4 AGREE THAT SHOULD BE PART OF THE CONSTRUCTION.

5 MR. RABINOWITZ: YES.

6 GILEAD'S PROPOSED CONSTRUCTION CONTAINS THOSE WORDS BUT
7 THEN IT HAS ADDITIONAL LANGUAGE WHICH I'VE REFLECTED THERE ON
8 THE SLIDE, SETTING THEM SIDE BY SIDE.

9 AND I WOULD LIKE TO JUST SET THE CONTEXT THEN GO INTO
10 MORE DETAIL TO IDENTIFY WHAT IT IS ABOUT GILEAD'S PROPOSED
11 CONSTRUCTION THAT WE THINK IS INCORRECT.

12 THE COURT: WELL, I GUESS, YOU KNOW, THIS IS WHERE MY
13 FIRST QUESTION IS.

14 IF I WERE TO ACCEPT YOUR DEFINITION, AND ITS SIMPLICITY
15 IS VERY APPEALING UNDER THE LAW AND THE DIRECT ROUTE TO
16 OBTAINING IT IS VERY APPEALING, BUT IT DOESN'T SEEM TO ADDRESS
17 OR RESOLVE THE ISSUES THAT GILEAD FEELS ARE IMPORTANT IN THIS
18 CASE, WHICH IS FINE BECAUSE CLAIMS CONSTRUCTION IS NOT THE
19 BEGINNING AND THE END OF ALL DISPUTES IN PATENT LITIGATION.

20 MR. RABINOWITZ: I THINK YOUR HONOR, THAT IN THE
21 COURSE OF ADOPTING THAT PROPOSED CONSTRUCTION, VERBATIM FROM
22 THE SPECIFICATION, COURTS OFTEN ISSUE REASONED OPINIONS ON
23 CLAIM CONSTRUCTION EXPLAINING WHY CERTAIN PROPOSALS ARE
24 REJECTED AND WOULD MAKE IT CRYSTAL CLEAR AND PROVIDE THE JURY
25 WITH A SIMPLE DEFINITION THAT THEY COULD USE TO TEST.

1 BECAUSE THE ISSUE OF INFRINGEMENT IS A QUESTION OF FACT
2 FOR THE JURY, AND THIS IS ALL ABOUT PROVIDING THE JURY
3 INSTRUCTION SO THAT THE JURY CAN EVALUATE WHETHER THE EVIDENCE
4 OF INFRINGEMENT TENDERED SATISFIES THE REQUIREMENTS OF THE
5 CLAIM.

6 THE COURT: SO YOU'RE REALLY SUGGESTING THAT BECAUSE
7 THE WORDS "IN COMBINATION WITH" IS THIS LONG CONTINUUM OF
8 ACTIVITY, IF YOU WILL, DURING THE COURSE OF TREATMENT, THAT
9 "ADMINISTERING" HAS THAT SAME HIGHWAY OF ACTIVITY.

10 MR. RABINOWITZ: WELL, IN COMBINATION WITH IS TALKING
11 ABOUT GIVING THINGS AT SEPARATE TIMES. ADMINISTERING DEALS
12 WITH ANOTHER ISSUE, IT'S AN EXPRESSLY DEFINED TERM AND IT SAYS
13 YOU CAN PROVIDE A COMPOUND OF THE INVENTION.

14 AND THE TERM COMPOUND OF THE INVENTION IS PATENT EASE FOR
15 CLAIMS COMPOUND, IT MEANS COMPOUND DEFINED BY THE CLAIM.

16 THE COURT: AND I PRESUME THAT THE TRIPHOSPHATE IS A
17 COMPOUND OF THE INVENTION.

18 MR. RABINOWITZ: IT IS.

19 THE COURT: THAT IS WITHOUT DISPUTE.

20 MR. RABINOWITZ: IT IS.

21 THE COURT: AND SO THIS WHOLE CASE COMES DOWN TO
22 WHETHER EVERY CONCEIVABLE PRODRUG, WHETHER KNOWN OR TO BE KNOWN
23 IN THE FUTURE, IS -- THAT BECOMES TRIPHOSPHATE THROUGH ANY
24 MEANS IS PATENTED BY MERCK.

25 MR. RABINOWITZ: WELL, I WOULD DISAGREE WITH THAT,

1 YOUR HONOR, BECAUSE CLAIM 1, AND IT'S IMPORTANT TO, IN FACT I
2 HAVE THE TEXT OF CLAIM 1, NEXT, CLAIM 1 IS DIRECTED TO A METHOD
3 OF TREATMENT. IT'S A PROCESS CLAIM, IT'S NOT -- THE OTHER
4 PATENT IS DIRECTED TO COMPOSITION OF MATTER CLAIMS, COMPOUNDS
5 AS SUCH. BUT CLAIM 1 OF THE '499 PATENT IS DIRECTED TO A
6 METHOD OF TREATING.

7 AND THERE'S AN IMPORTANT DIFFERENCE IN THAT, FOR EXAMPLE,
8 YOU CAN HAVE A PATENT ON A NEW METHOD OF USING AN OLD COMPOUND,
9 IF YOU DISCOVER WHAT IT CAN BE USED FOR.

10 THE COURT: SO METHOD BEING THE USE OF A PRODRUG THAT
11 TRANSFORMS -- WELL, BY DEFINITION A PRODRUG TRANSFORMS IN VIVO.

12 MR. RABINOWITZ: SO THERE'S A FUNDAMENTAL DISCOVERY
13 MADE BY THE MERCK AND ISIS SCIENTISTS. THEY DISCOVERED BY
14 PUTTING CERTAIN CHEMICAL GROUPS ONTO A CLASS OF COMPOUNDS
15 CALLED NUCLEOSIDE ANALOGS, IT'S THE KIND OF STRUCTURES THAT
16 GILEAD SHOWED YOU LAST WEEK, THEY OBTAINED A COMPOUND THAT
17 INHIBITS AN IMPORTANT ENZYME OF HEPATITIS C VIRUS, AND THAT
18 PROVIDES A METHOD OF TREATING HEPATITIS C VIRUS INFECTION.

19 SO WHAT THEY DISCLOSED IN THEIR SPECIFICATION AND ARE
20 CLAIMING IN THIS PATENT IS A METHOD OF TREATING HEPATITIS C
21 VIRUS INFECTION BY PROVIDING A COMPOUND WITH, THEY SET OUT THE
22 SALIENT FEATURES OF THE COMPOUND IN THE STRUCTURAL FORMULA, AND
23 THE SPECIFICATION MAKES IT CLEAR, OUR DISCOVERY IS THAT THESE
24 COMPOUNDS HAVING THESE FEATURES WILL BE BENEFICIAL AGAINST THE
25 VIRUS. YOU PROVIDE THEM, YOU CAN PROVIDE THEM THE COMPOUNDS

1 THEMSELVES OR YOU CAN USE WHAT'S CALLED A PRODRUG STRATEGY.

2 THE COURT: BUT THIS CASE IS NOT THE PRODRUG
3 STRATEGY.

4 MR. RABINOWITZ: WELL, IT'S ABOUT WHETHER THIS CLAIM
5 INCLUDES THIS METHOD OF TREATMENT WHEN PERFORMED BY
6 ADMINISTERING A PRODRUG THAT CONVERTS INTO A COMPOUND OF THE
7 INVENTION LIKE THE TRIPHOSPHATE.

8 SO THE INFRINGEMENT ISSUE, OUR THEORY OF INFRINGEMENT IS
9 WHEN SOFOSBUVIR IS PROVIDED, IT IS A PRODRUG THAT CONVERTS
10 AFTER IT'S SWALLOWED INTO THE MONOPHOSPHATE, THE DIPHOSPHATE,
11 AND THE TRIPHOSPHATE. THE MONOPHOSPHATE AND THE DIPHOSPHATE
12 ARE COMPOUNDS OF THE INVENTION ALSO BUT ARE NOT THEMSELVES
13 ACTIVE DRUGS. THEY ARE, IN FACT, PRODRUGS THAT CONVERT TO THE
14 TRIPHOSPHATE WHICH IS ACTIVE.

15 AND SO WE WOULD VIEW THIS AS LITERALLY PERFORMING THIS
16 CLAIMED METHOD BY PROVIDING A PRODRUG, SOFOSBUVIR, OF A
17 COMPOUND OF THE INVENTION. IT'S, IN FACT, A PRODRUG OF THREE
18 COMPOUNDS OF THE INVENTION, THE MONOPHOSPHATE, THE DIPHOSPHATE
19 AND THE TRIPHOSPHATE

20 THE COURT: IN THE BRIEFING THERE WAS QUITE A
21 DISCUSSION, INCLUDING MERCK'S OWN HANDBOOK, AS TO WHETHER THE
22 ACT OF ADMINISTERING ENDS AT THE ENTRY POINT TO THE HUMAN BODY.

23 MR. RABINOWITZ: THAT'S A COMPLETE RED HERRING,
24 YOUR HONOR, LET ME EXPLAIN WHY.

25 LET'S IMAGINE THE PATIENT SWALLOWS A PILL AT MIDNIGHT.

1 WE WANT TO KNOW WHETHER, LET'S SAY, TO MAKE IT CLEAR, THAT THE
2 NURSE GIVES THE -- PROVIDES THE PATIENT WITH A PILL AT MIDNIGHT
3 WHICH THE PATIENT SWALLOWS IMMEDIATELY.

4 WE WANT TO KNOW WHETHER PROVIDING THAT PILL WITH
5 SOFOSBUVIR WAS AN ACT OF INFRINGEMENT AT MIDNIGHT. WE NEED TO
6 ANSWER THAT QUESTION -- TO ANSWER THAT QUESTION, WE NEED TO
7 KNOW WHETHER SOFOSBUVIR IS A PRODRUG OF THE COMPOUND OF THE
8 INVENTION. IF IT WAS, PROVIDING IT WAS AN ACT OF INFRINGEMENT.

9 SO IT'S NOT A MATTER OF WHEN THE ACT OF INFRINGEMENT
10 OCCURS, IT'S A MATTER OF WHAT CONSTITUTES AN ACT OF
11 INFRINGEMENT.

12 THE COURT: BECAUSE THE KNOWN CONSEQUENCE OF THE
13 ADMINISTRATION OF IT IS THE INFRINGEMENT.

14 MR. RABINOWITZ: AS PROFESSOR WUEST EXPLAINED TO YOU
15 LAST WEEK, THE VERY PHRASE "PRODRUG OF A COMPOUND" MEANS ONLY
16 ONE THING, IT MEANS ONE COMPOUND, THE PRODRUG THAT IS
17 TRANSFORMED OR CONVERTED BY METABOLISM INTO ANOTHER.

18 IT'S LIKE SAYING YOU CAN'T INTERPRET THE PHRASE "PARENT
19 OF THE CHILD" WITHOUT REGARD TO THE DESCENDANTS OF THE PERSON
20 IN QUESTION. IT'S NOT A MATTER OF WHEN THEY HAVE CHILDREN,
21 IT'S A MATTER OF WHETHER THEY HAVE CHILDREN.

22 SO THIS IS NOT A MATTER OF WHEN THE PRODRUG CONVERTS TO
23 THE COMPOUND OF THE INVENTION, IT'S A MATTER OF WHETHER IT
24 DOES.

25 THE COURT: OKAY. GO AHEAD.

1 MR. RABINOWITZ: SO HAVING SET THE CONTEXT OF THE
2 TERM, IT IS AS WE POINT OUT, AND I DON'T THINK THIS IS DENIED,
3 EXPRESSLY DEFINED IN THE SPECIFICATION.

4 AND IT'S DEFINED SO THAT IT'S CLEAR IT CAN BE, THAT
5 ADMINISTERING CAN BE ACCOMPLISHED IN TWO WAYS.

6 SO ADMINISTERING A COMPOUND SHOULD BE UNDERSTOOD TO MEAN,
7 AND THE FIRST WAY IS PROVIDING A COMPOUND OF THE INVENTION, OR
8 A PRODRUG OF A COMPOUND OF THE INVENTION TO THE INDIVIDUAL IN
9 NEED.

10 THE COURT: AND SO THAT WOULD BE THE ENTIRE UNIVERSE
11 OF PRODRUGS THAT TRANSFORM INTO COMPOUNDS OF THE INVENTION.

12 MR. RABINOWITZ: AGAIN, IT WOULDN'T COVER THE
13 PRODRUGS THEMSELVES.

14 SO IF YOU USED A PRODRUG FOR TREATING HEPATITIS B, IT
15 WOULD NOT FALL WITHIN THE SCOPE OF THIS CLAIM. REMEMBER THE
16 CLAIM IS DIRECTED TO A METHOD OF TREATING HEPATITIS C VIRUS.

17 THE COURT: OH, I SEE.

18 SO IF IT WERE DETERMINED AT SOME FUTURE DATE THAT
19 TRIPHOSPHATE ALSO TREATS SOME DIFFERENT DISEASE, YOU WOULDN'T
20 SAY THAT THIS IS NOT INFRINGEMENT.

21 MR. RABINOWITZ: THAT'S EXACTLY RIGHT.

22 THERE ARE MANY INSTANCES LIKE THAT, THE MINOXIDIL, THE
23 HAIR RESTORER, WAS ACTUALLY BEING TESTED AS I THINK AN
24 ANTIHYPERTENSIVE AGENT.

25 IT'S OFTEN THE CASE THAT DRUGS MAY HAVE MULTIPLE AND

1 PERHAPS UNEXPECTED EFFECTS, BENEFICIAL EFFECTS OR SIDE EFFECTS.

2 AND SO IF YOU DISCOVER A NEW USE FOR AN OLD COMPOUND,
3 THAT'S ACTUALLY IN THE STATUTE, A NEW USE FOR AN OLD PRODUCT,
4 THAT LEADS TO A METHOD OF TREATMENT CLAIM.

5 AND SO THAT'S WHY IT'S IMPORTANT, THIS SAYS NOTHING ABOUT
6 ANY OTHER USE THAT MAY BE MADE OF A PRODRUG OR INDEED A
7 COMPOUND.

8 THE COURT: OKAY.

9 MR. RABINOWITZ: IT'S A METHOD OF TREATMENT CLAIM.

10 SO -- AND SO THIS METHOD OF TREATMENT CAN BE CARRIED OUT
11 AS CLAIMED IN TWO WAYS, EITHER BY PROVIDING TO THE PATIENT,
12 HAVING A HEPATITIS C VIRUS INFECTION, A COMPOUND OF THE
13 INVENTION, OR A PRODRUG OF A COMPOUND OF THE INVENTION.

14 SO LET'S JUST LOOK AT SOME BASIC FUNDAMENTAL CLAIM
15 CONSTRUCTION TO SEE WHAT THE IMPLICATION OF THIS IS. THIS
16 IS -- SPECIFICATIONS CAN DEFINE TERMS IMPLICITLY, BUT THIS IS
17 AN EXPRESS DEFINITION.

18 AND THERE'S A HIERARCHY OF TOOLS FOR PERFORMING CLAIM
19 CONSTRUCTION THAT THE FEDERAL CIRCUIT HAS DEFINED. INTRINSIC
20 EVIDENCE OUTWEIGHS EXTRINSIC EVIDENCE, IT TRUMPS IT. AND IN
21 THE HIERARCHY, THE SPECIFICATION IS AT THE TOP.

22 AND THE LEADING CASE WHICH IS THE EN BANC OPINION IN
23 PHILLIPS V. AWH CORP, THE FEDERAL CIRCUIT SAID THE
24 SPECIFICATION IS ALWAYS HIGHLY RELEVANT TO THE CLAIM
25 CONSTRUCTION ANALYSIS, USUALLY IT IS DISPOSITIVE, IT IS THE

1 SINGLE BEST GUIDE TO THE MEANING OF A DISPUTED TERM. AND
2 THAT'S WITHOUT EVEN CONFINING THAT PRINCIPLE TO SPECIFICATIONS
3 THAT HAVE EXPRESSED DEFINITIONS.

4 THE NEXT QUOTE FROM PHILLIPS, AND I APOLOGIZE IT'S
5 ACTUALLY AT 1316, NOT PAGE 1315, IS DEFINES, IT'S A HUMPTY
6 DUMPTY WORLD. IF YOU REMEMBER ALICE THROUGH THE LOOKING GLASS,
7 HUMPTY DUMPTY SAID TO ALICE, WHEN I USE A WORD, IT MEANS
8 WHATEVER I SAY IT MEANS.

9 WELL, THE FEDERAL CIRCUIT HAS SAID THAT AN INVENTOR COULD
10 BE HIS OWN LEXICOGRAPHER AND NARRATE, AND THIS IS AN
11 ENFORCEMENT OF THAT PRINCIPLE.

12 AND THE FEDERAL CIRCUIT SAID, OUR CASES RECOGNIZE THAT
13 THE SPECIFICATION MAY REVEAL A SPECIAL DEFINITION GIVEN TO THE
14 CLAIM TERM BY THE PATENTEE THAT DIFFERS FROM THE MEANING IT
15 WOULD OTHERWISE POSSESS; IN SUCH CASES, THE INVENTOR'S
16 LEXICOGRAPHY GOVERNS.

17 AND THAT'S WHY IT'S IRRELEVANT WHAT THE MERCK MANUAL SAYS
18 "ADMINISTERING" NORMALLY MEANS. THE MERCK MANUAL IS AN
19 EXCELLENT SOURCE PUBLISHED BY MERCK.

20 THE COURT: WELL, MERCK ISN'T THE PATENTEE.

21 MR. RABINOWITZ: IT IS.

22 THE COURT: THIS ISN'T ONE YOU BOUGHT, THIS IS ONE
23 THAT YOU ACTUALLY DEVELOPED?

24 MR. RABINOWITZ: THIS WAS THE RESULT OF A JOINT
25 RESEARCH PROGRAM THAT WE SPENT YEARS AT MERCK AND ISIS AND WAS

1 AN EXTREMELY IMPORTANT COLLABORATION BETWEEN THEM.

2 SO THE MERCK MANUAL, I WOULD SAY IT'S AN UNIMPEACHABLE
3 SOURCE GIVEN WHERE ITS PROVINCE IS, BUT IT DOESN'T ADDRESS THE
4 MEANING OF "ADMINISTERING," IN A PATENT WHICH HAS A SPECIAL
5 DEFINITION WHICH UNDER PHILLIPS DISPLACES THE ORDINARY MEANING.

6 THE COURT: WELL, I WOULD ABSOLUTELY AGREE WITH THAT.
7 THE MERCK MANUAL HAS BEEN UTILIZED AND DEFINED BY THE FEDERAL
8 CIRCUIT, BUT I WOULD AGREE CERTAINLY IN THIS PATENT MERCK WAS
9 FREE OR THE PATENTEE WAS FREE TO DEPART FROM A MORE GENERIC OR
10 EVEN COMMON UNDERSTANDING OF A TERM.

11 MR. RABINOWITZ: YES.

12 AND WHAT YOUR HONOR IS REFERRING TO, THERE'S A PRINCIPLE
13 THAT TERMS ARE PRESUMED TO HAVE THEIR ORDINARY MEANING IN THE
14 FIELD, AND YOU LOOK AT RELIABLE SOURCES IN THE RELEVANT FIELD
15 OF ENDEAVOR, UNLESS THE SPECIFICATION EITHER IMPLICITLY OR
16 EXPRESSLY GIVES THEM DIFFERENT MEANING. AND HERE THIS IS
17 EXPRESSLY DONE.

18 SO THE ORDINARY MEANING IS IRRELEVANT, AND I WOULD SAY IS
19 NOT REALLY A FIT SUBJECT FOR INQUIRY IN THE CONTEXT OF THIS
20 PATENT BECAUSE THERE IS AN EXPRESS DEFINITION IN THE
21 SPECIFICATION.

22 THE COURT: YEAH. OKAY.

23 MR. RABINOWITZ: AND THE OTHER THING THAT IS
24 IMPORTANT, ALSO IN PHILLIPS, IS THAT, AND I KNOW THIS IS THE
25 DIFFICULTY WITH CLAIM CONSTRUCTION IN TECHNICAL PATENTS, THE

1 COURT MUST UNDERSTAND WHAT THE SPECIFICATION SAYS FOR WHAT IT
2 CONVEYS TO A PERSON OF SKILL IN THAT RELEVANT FIELD.

3 AND SO THIS REALLY, THERE'S REALLY THREE QUOTES FROM THE
4 SAME PLACE IN THE PHILLIPS CASE, THE THIRD IS THE MOST
5 IMPORTANT.

6 THE FEDERAL CIRCUIT HAS EXPLAINED IT IS THE PERSON OF
7 ORDINARY SKILL IN THE FIELD OF THE INVENTION THROUGH WHOSE EYES
8 THE CLAIMS ARE CONSTRUED. SUCH A PERSON IS DEEMED TO READ THE
9 WORDS USED IN THE PATENT DOCUMENTS WITH AN UNDERSTANDING OF
10 THEIR MEANING IN THE FIELD, AND TO HAVE KNOWLEDGE OF ANY
11 SPECIAL MEANING AND USAGE IN THE FIELD.

12 AND THIS RELATES REALLY TO THE WORD "PRODRUG" WHICH IS
13 PART OF THE DEFINITION.

14 THE COURT: WELL, I DON'T THINK ANYONE DISAGREES WITH
15 WHAT A PRODRUG IS.

16 MR. RABINOWITZ: BUT IT'S IMPORTANT, AND THIS IS THE
17 CASE LAW PRECEDENT THAT EMPHASIZES THE COURT, IN CONSTRUING THE
18 DEFINITION, MUST UNDERSTAND WHAT A PRODRUG OF A COMPOUND MEANS
19 AS A PERSON OF SKILL IN THE FIELD OF MEDICINAL CHEMISTRY WOULD
20 UNDERSTAND THAT PHRASE.

21 THE COURT: WELL, AND DO I HAVE A DECLARATION FROM
22 YOUR EXPERT THAT SETS THIS OUT.

23 MR. RABINOWITZ: NOT A DECLARATION, YOU HAVE AN
24 EXPLANATION. AND YOU HAVE -- WE SUBMITTED WITH OUR OPENING
25 BRIEF, AND I WILL COME TO THAT IN A SECOND, A REVIEW ARTICLE BY

1 PROFESSOR STELLAR, THE DEFINITION PROVIDED BY DR. WUEST IS
2 PERHAPS MORE ACCESSIBLE.

3 THE COURT: BUT WHAT DR. WUEST TOLD ME LAST WEEK IS
4 NOT EVIDENCE FOR CLAIMS CONSTRUCTION, LET'S NOT CONFUSE THAT.

5 MR. RABINOWITZ: IT WASN'T EVIDENCE, BUT YOU HAVE
6 DOCUMENTARY EVIDENCE IN THE RECORD ABOUT WHAT THE ORDINARY
7 MEANING OF PRODRUG IS IN THE FORM OF PROFESSOR STELLAR'S REVIEW
8 ARTICLE WHICH WE SUBMITTED WITH OUR OPENING BRIEF.

9 THAT, I THINK, IS NOT BEING DENIED OR DISPUTED WITH
10 GILEAD. THEY TOOK NO ISSUE WITH THAT IN THEIR OPPOSING BRIEF.

11 AND SO THIS IS WHAT I THINK GOVERNS HERE, THE THIRD
12 QUOTE, THE INVENTOR'S WORDS, THEY ARE USED TO DESCRIBE THE
13 INVENTION, THE INVENTOR'S LEXICOGRAPHER MUST BE UNDERSTOOD AND
14 INTERPRETED BY THE COURT AS THEY WOULD BE UNDERSTOOD AND
15 INTERPRETED BY A PERSON IN THAT FIELD OF TECHNOLOGY.

16 SO THAT'S WHAT'S GOING ON IN THE DEFINITION OF PRODRUG.
17 AND I WILL COME TO THAT IN A FEW SLIDES IF YOU WILL PERMIT.

18 SO LET ME JUST AGAIN EMPHASIZE THAT MERCK'S PROPOSED
19 DEFINITION IS, TAKEN VERBATIM FROM THE SPECIFICATION. GILEAD'S
20 PROPOSED DEFINITION IS NOT, AND IT INCLUDES TWO ADDITIONAL
21 PHRASES, AND I WANT TO DISCUSS THEM SEPARATELY. THEY REALLY
22 ARE TWO ADDITIONAL LIMITATIONS.

23 THE FIRST LIMITATION IS THAT SOMEHOW THE DEFINITION WHICH
24 INCLUDES THE PHRASE "PRODRUG OF A COMPOUND," MUST BE UNDERSTOOD
25 WITHOUT REFERENCE TO IN VIVO TRANSFORMATION OF THOSE COMPOUNDS

1 OR PRODRUGS. AND THAT'S WHAT I WILL DISCUSS FIRST, THEN I WILL
2 DEAL WITH THE SECOND LIMITATION AFTER.

3 SO LET'S JUST TALK ABOUT THE FIRST ONE, WITHOUT REFERENCE
4 TO IN VIVO TRANSFORMATION OF THOSE COMPOUNDS OR PRODRUGS.

5 WE SUBMIT THAT IS INCONSISTENT WITH THE VERY NATURE OF A
6 PRODRUG. AND HERE'S THE EXPLANATION GIVEN BY PROFESSOR WUEST
7 WHICH WAS NOT EVIDENCE, TOGETHER WITH IN THE SECOND BULLET
8 POINT, THE DEFINITION GIVEN BY THE REVIEW ARTICLE BY PROFESSOR
9 STELLAR THAT WE SUBMITTED. AND THEY BOTH SAY THE SAME THING,
10 "A PRODRUG IS A MEDICATION ADMINISTERED IN A PHARMACOLOGICALLY
11 INACTIVE FORM WHICH IS THEN CONVERTED INTO ACTIVE FORM BY A
12 NORMAL METABOLIC PROCESS."

13 THE COURT: I DON'T THINK THAT'S DISPUTED. I DON'T
14 THINK IT IS AT ALL.

15 AND I THINK I UNDERSTOOD IT, MAYBE ONE OF THE FEW THINGS
16 I CAN SAY WITH CONFIDENCE I DID UNDERSTAND IN THE SCIENCE, BUT
17 I GET THAT.

18 MR. RABINOWITZ: SO YOU KNOW, SO WE ARE RELYING, IF
19 YOU LIKE, AND PROFESSOR STELLAR'S QUOTE ADDRESSES IT EVEN MORE
20 DIRECTLY BECAUSE HE SAID PRODRUGS MUST UNDERGO CHEMICAL
21 TRANSFORMATION WITHIN THE BODY PRIOR TO EXERTING THEIR
22 PHARMACOLOGICAL OR THERAPEUTIC ACTION.

23 SO WHEN THE SPECIFICATION SAYS TO A PERSON OF SKILL IN
24 THIS FIELD, YOU CAN ACCOMPLISH THE METHOD OF ADMINISTERING BY
25 PROVIDING TO THE PATIENT A PRODRUG OF A COMPOUND OF THE

1 INVENTION, THIS MEANS A PRODRUG WHICH MUST UNDERGO CHEMICAL
2 TRANSFORMATION.

3 THE COURT: IT SEEMS TO ME IT MUST, OTHERWISE IT'S
4 JUST A DRUG.

5 MR. RABINOWITZ: OTHERWISE IT'S JUST A DRUG, EXACTLY.

6 SO THAT'S WHY WE BELIEVE THAT ADDING A LIMITATION TO THAT
7 DEFINITION THAT SAYS, WITHOUT REFERENCE TO IN VIVO
8 TRANSFORMATION, IS ANTITHETICAL TO THE VERY IDEA OF A PRODRUG.

9 THE COURT: SO HERE YOUR NUMBER 2, THE SECOND ISSUE,
10 THE INTERESTING THING TO ME IS CERTAINLY IT'S TRUE THAT GILEAD
11 IS INTRODUCING A CONCEPT HERE THAT IS BEYOND THE
12 SPECIFICATION'S DEFINITION.

13 BUT WHAT I WAS INTERESTED IN IN YOUR OWN BRIEF IS THAT
14 YOU, ON PAGE 10 OF YOUR REPLY BRIEF, TOLD ME WHAT THE PHRASE,
15 PRODRUG OF A COMPOUND OF THE INVENTION MEANS.

16 AND THAT'S AT THE -- AT LINES 18 AND 19, ON PAGE 10.

17 MR. RABINOWITZ: AND THAT IS EXACTLY. THAT APPLIES
18 THE ORDINARY MEANING OF PRODRUG TO THE PHRASE --

19 THE COURT: SO HERE'S MY QUESTION, AND I'M SOUNDING
20 LIKE A BROKEN RECORD ON IT, I GUESS, UNTIL I FEEL LIKE I HAVE
21 AN ANSWER, I WILL KEEP ASKING.

22 GILEAD IS GIVING ME A DEFINITION OF PRODRUG OF A COMPOUND
23 AND YOU ARE TOO, AND YET YOU ARE TELLING ME THAT YOU DON'T WANT
24 ME TO CONSTRUE THAT TERM.

25 AND YET WHEN YOU STAND BEFORE THE JURY WITH YOUR

1 DEFINITION, IF I ADOPT THAT AS THE CONSTRUCTION OF
2 ADMINISTERING, THE TERM PRODRUG OF A COMPOUND OF THE INVENTION
3 IS EMBEDDED IN YOUR DEFINITION. AND I WILL HAVE NOT GIVEN THE
4 JURY ANY DEFINITION OF THAT TERM PRODRUG OF A COMPOUND OF THE
5 INVENTION.

6 AND SO I GET BACK TO THIS, WILL EACH OF YOU THEN BE FREE
7 TO ARGUE YOUR OWN DEFINITION OF THAT TERM TO THE JURY?

8 MR. RABINOWITZ: NO, YOUR HONOR.

9 WE THINK THAT THE COURT SHOULD RESOLVE THAT ISSUE BY
10 ISSUING A MARKMAN OPINION REJECTING GILEAD'S PROPOSED
11 LIMITATION.

12 AND IF THE COURT WISHES TO CLARIFY THE CONSTRUCTION FOR
13 THE BENEFIT OF THE JURY, OR ONCE THE COURT HAS ISSUED A RULING,
14 WE WILL PROPOSE JURY INSTRUCTIONS TO THE JURY WHICH MAKES IT
15 CLEAR THAT THE COURT WILL HAVE RESOLVED THAT ISSUE AS A RESULT
16 OF THIS PROCEEDING.

17 THE COURT: AND SO IN FACT YOU ARE BOTH ASKING ME TO
18 CONSTRUE THAT TERM. YOU ARE BOTH ASKING THAT BECAUSE BY
19 REJECTING GILEAD'S, I MUST ACCEPT YOUR DEFINITION OF THAT TERM.

20 MR. RABINOWITZ: WE HAVE NO OBJECTION IF THE COURT
21 ISSUES AN OPINION SAYING "PRODRUG OF A COMPOUND OF THE
22 INVENTION MEANS, THEN TAKES IT'S ORDINARY MEANING FROM OUR
23 BRIEF OR PROFESSOR STELLAR ARTICLE.

24 THE COURT: HERE'S MY CONCERN. IF YOU ARE BOTH
25 ACTUALLY ASKING ME TO CONSTRUE THAT TERM, I WOULD CONSTRUE THAT

1 TERM SEPARATELY FROM THE TERM ADMINISTERING, BECAUSE TO ME
2 ADMINISTERING IS AN ACT THAT, AS YOU SAY, IS INFORMED BY ITS
3 CONSEQUENCES.

4 BUT YOU ARE REALLY TALKING ABOUT ADMINISTERING, GIVING
5 THAT TABLET TO THE PATIENT TO SWALLOW IS AN ACT OF
6 INFRINGEMENT, BECAUSE WE KNOW THE CONSEQUENCE OF SWALLOWING THE
7 PILL IS TO SET IN MOTION THE IN VIVO TRANSFORMATION THAT
8 BECOMES THE COMPOUND OF THE INVENTION

9 MR. RABINOWITZ: YOUR HONOR, I WOULD DISAGREE
10 SLIGHTLY BECAUSE THE PHRASE IN THE PATENT IS "ADMINISTERING A
11 COMPOUND." IN THE CLAIM. THE WORD -- THAT'S WHY I GAVE YOU
12 THE CONTEXT OF ADMINISTERING TO A MAMMAL IN NEED THEREOF, A
13 THERAPEUTICALLY EFFECTIVE AMOUNT OF A COMPOUND.

14 AND SO THAT'S WHY THE SPECIFICATION SPEAKS TO WHAT IT
15 MEANS TO ADMINISTER A COMPOUND.

16 THE COURT: SO A PRODRUG IS A COMPOUND.

17 MR. RABINOWITZ: YES.

18 SO IT SAYS A COMPOUND OF STRUCTURAL FORMULA III, THAT
19 DEFINES WHAT A COMPOUND OF THE INVENTION IS.

20 THE COURT: SO THAT'S A LIMITATION.

21 MR. RABINOWITZ: SO CERTAIN COMPOUNDS DEFINED BY THE
22 STRUCTURAL FORMULA ARE COMPOUNDS OF THE INVENTION FOR PURPOSES
23 OF THIS CLAIM. EACH CLAIM DEFINES THE INVENTION BEING
24 PROTECTED BY THAT CLAIM.

25 THE COURT: AND THAT'S AN EXPRESS LIMITATION OF THE

1 WORD COMPOUND.

2 MR. RABINOWITZ: YES. THAT DEFINES A COMPOUND OF THE
3 INVENTION.

4 THEN ADMINISTERING SAYS YOU CAN ACCOMPLISH THIS EITHER BY
5 PROVIDING THAT COMPOUND OF THE INVENTION OR A PRODRUG OF THE
6 COMPOUND OF THE INVENTION.

7 AND SO THE DEFINITION OF ADMINISTERING DESCRIBES THE --
8 WHAT IS IT THAT SATISFIES THE CLAIMS REQUIREMENT THAT YOU
9 ADMINISTER A COMPOUND OF THE INVENTION.

10 AND THE SPECIFICATION SAYS YOU CAN DO IT BY PROVIDING
11 THAT COMPOUND OR PROVIDING A PRODRUG OF THAT COMPOUND.

12 THE COURT: SO IF ONE ADMINISTERS COUGH SYRUP, THAT'S
13 NOT, IT DOESN'T MATTER, THAT'S NOT ADMINISTERING IN THE TERMS
14 OF THIS.

15 MR. RABINOWITZ: IT'S NOT ADMINISTERING THE COMPOUND
16 OF THE INVENTION BECAUSE IT NEITHER CONTAINS SUCH A COMPOUND
17 NOR DOES IT CONTAIN A PRODRUG.

18 THE COURT: AND IS IT DOESN'T TREAT THIS ILLNESS.

19 MR. RABINOWITZ: IT WOULDN'T BE THERAPEUTICALLY
20 EFFECTIVE EITHER.

21 THE COURT: OKAY. ALL RIGHT.

22 MR. RABINOWITZ: SO I DO THINK THE COURT HAS TO
23 RESOLVE THIS ISSUE.

24 THE COURT: I THINK SO TOO.

25 AND -- BECAUSE AT A SUPERFICIAL LEVEL IT APPEARS THAT I

1 COULD SIMPLY, IF I GO YOUR WAY, ADOPT YOUR CONSTRUCTION, CITE
2 PHILLIPS, CITE THE SPECIFICATION AND DO NOTHING MORE.

3 MR. RABINOWITZ: WE WOULD LIKE YOU TO EXPLAIN THAT
4 THE PROPOSED LIMITATIONS, IT NEEDN'T BE IN THE FORMAL PHRASE
5 WHICH CONSTRUES THE CLAIMS, BUT THE MARKMAN ORDER WOULD
6 CONSIDER AND REJECT THOSE PROPOSED LIMITATIONS TO SAY THAT THE
7 PHRASE, THE CLAIM DOES NOT INCLUDE THOSE LIMITATIONS, AND THAT
8 WOULD GIVE US GUIDANCE FOR PROPOSING JURY INSTRUCTIONS THAT ARE
9 CONSISTENT WITH YOUR HONOR'S RULING.

10 THAT'S THE BENEFIT OF DOING MARKMAN IN ADVANCE,
11 OTHERWISE, THERE'S NO REQUIREMENT MARKMAN CAN BE DONE AT THE
12 THRESHOLD, ONE CAN DO IT IN THE COURSE OF ADOPTING JURY
13 INSTRUCTIONS, THEN OF COURSE ONE PLAIN SIMPLE INSTRUCTION THAT
14 ARE SUITABLE TO GIVE TO THE JURY.

15 THE COURT: THE ENORMITY OF THAT TASK AND THE BURDEN
16 ON COUNSEL TO PREPARE YOUR CASE TO THE JURY AT THE LAST MINUTE
17 WOULD BE EXTRAORDINARY.

18 MR. RABINOWITZ: IT IS SOMETIMES MUCH MORE CONVENIENT
19 TO DO IT THIS WAY ESPECIALLY BECAUSE, YOU KNOW, IN ADVANCE OF
20 THE EXPERT REPORTS, WHAT THE CLAIMS MEAN FOR PURPOSES OF THE
21 CASE.

22 THE COURT: SURE.

23 MR. RABINOWITZ: SO I THINK IT WOULD BE HELPFUL --

24 THE COURT: AND SO YOU ARE ASKING ME TO REJECT IT
25 BECAUSE IT'S OUTSIDE THE DEFINITION ITSELF.

1 MR. RABINOWITZ: IT'S INCOMPATIBLE WITH THE
2 DEFINITION ITSELF, NOT JUST THAT IT'S EXTRANEIOUS, IT'S
3 INCONSISTENT WITH, CANNOT BE SQUARED WITH THE DEFINITION.

4 AND THE FIRST LIMITATION IS ANTITHETICAL TO THE VERY
5 NOTION OF A PRODRUG. I SUBMIT YOU CANNOT POSSIBLY UNDERSTAND
6 WHAT A COMPOUND OF A PRODRUG IS WITHOUT TAKING INTO ACCOUNT HOW
7 THE PRODRUG IS TRANSFORMED TO SEE WHETHER IT IS A PRODRUG OF A
8 COMPOUND.

9 IF YOU SIMPLY IGNORE AND ERASE FROM YOUR CONSCIENCE WHAT
10 HAPPENS TO THE PRODRUG AFTER IT'S ABSORBED INTO THE BODY, YOU
11 CANNOT POSSIBLY TELL WHETHER IT'S A PRODRUG OF A PARTICULAR
12 COMPOUND OR NOT. YOU ONLY KNOW BY KNOWING WHETHER IT GETS
13 CONVERTED.

14 THE COURT: I GUESS I'M FEELING THAT, I COULD BE
15 WRONG, I KNOW I'M JUMPING AHEAD, THAT IF I ADOPT YOUR
16 DEFINITION AND GO THE NEXT STEP OF REJECTING, ESPECIALLY THE
17 SECOND PORTION OF GILEAD'S, THIS CASE IS ESSENTIALLY OVER.

18 MR. RABINOWITZ: WE THINK THAT THERE WILL -- WE DO
19 NOT KNOW HOW THERE COULD BE DISPUTED FACTS TO CONTRADICT THE
20 PROPOSITION THAT PATIENTS WHO USE SOFOSBUVIR DIRECTLY INFRINGE
21 THE CLAIMS OF THE COMPOSITION PATENT, WHICH NOW WE JUST DON'T
22 ACCEPT A DEFINITION OF COMPOUND, THEY ARE LITERALLY MAKING IN
23 THEIR BODIES AND USING COMPOUNDS THAT ARE CLAIMED.

24 AND WE THINK THE SAME WOULD BE TRUE FOR DIRECT
25 INFRINGEMENT WITH THIS CLAIM UNDER OUR CONSTRUCTION.

1 THE COURT: WELL, IT --

2 MR. RABINOWITZ: WHICH IS, OF COURSE, WHY GILEAD HAS
3 AN INCENTIVE TO SEEK TO IMPORT LIMITATIONS.

4 THE COURT: AND IT PUTS IN SHARP RELIEF THE
5 IMPORTANCE OF THIS CONSTRUCTION BECAUSE IT DOES SEEM PIVOTAL IN
6 THE CASE. ALTHOUGH, OF COURSE I HAVEN'T REALLY SEEN YOUR
7 INFRINGEMENT ARGUMENTS HERE, BUT IT SEEMS LIKE THIS IS THE KEY
8 POINT.

9 MR. RABINOWITZ: WELL, I THINK THAT FROM THE CONTEXT
10 THAT WE'VE PROVIDED, ESPECIALLY GILEAD, IT SHOULD BE READILY
11 APPARENT THAT UNDER THE -- IF EFFECT IS GIVEN TO THE DEFINITION
12 IN THE SPECIFICATION, IT CERTAINLY DESCRIBES TREATING THE
13 PATIENT BY PROVIDING A PRODRUG OF THE TRIPHOSPHATE METABOLITE.

14 THE COURT: SO ANYTHING THAT BECOMES TRIPHOSPHATE IS
15 YOURS, ANYTHING THROUGH A PRODRUG?

16 MR. RABINOWITZ: NO, NO, ONLY TRIPHOSPHATE HAVING THE
17 PARTICULAR STRUCTURE THAT THE MERCK SCIENTISTS FOUND WILL MAKE
18 AN INHIBITOR.

19 LOTS OF THINGS ARE TRIPHOSPHATE OUTSIDE THE SCOPE OF
20 THESE CLAIMS. THESE ARE TRIPHOSPHATE OF A PARTICULAR TYPE.

21 THE COURT: OKAY. GO AHEAD.

22 MR. RABINOWITZ: SO -- AND JUST TO REMIND YOU, THIS
23 IS WHY WE THINK THAT THE NOTION OF NOT LOOKING AT
24 TRANSFORMATION IS ANTITHETICAL TO THE IDEA OF A PRODRUG.

25 ASPIRIN IS A PRODRUG OF SALICYLIC ACID. IF YOU HAD TO BE

1 BLIND TO WHAT HAPPENS AFTER YOU SWALLOW ASPIRIN, YOU COULDN'T
2 POSSIBLY TELL WHETHER IT'S A PRODRUG OF SALICYLIC ACID OR NOT.

3 THE WHOLE NOTION OF A PRODRUG REQUIRES ONE TO AVERT TO
4 WHETHER IT'S TRANSFORMED --

5 THE COURT: SO IT EXPLAINS WHY ONE IS TAKING THE
6 ASPIRIN IS BECAUSE ONE WANTS THE REMEDY THAT SALICYLIC ACID IS
7 GOING TO GIVE.

8 MR. RABINOWITZ: YES.

9 THE COURT: WELL, THAT'S RIGHT. YOU DON'T TAKE A
10 PRODRUG, IT DOES NOTHING ITSELF.

11 MR. RABINOWITZ: BY DEFINITION.

12 I MEAN, IF SOFOSBUVIR DIDN'T CONVERT TO THE TRIPHOSPHATE,
13 IT WOULD BE USELESS.

14 THE COURT: YES.

15 MR. RABINOWITZ: SO THE SECOND PART IS THAT GILEAD IS
16 TRYING TO REWRITE THE SECOND PART OF THE DEFINITION SO IT MEANS
17 EXACTLY THE SAME AS THE FIRST.

18 SO THEIR PROPOSED CONSTRUCTION SAYS THE PHRASE "PRODRUG
19 OF A COMPOUND MEANS THOSE PRODRUGS THAT ARE EXPRESSLY CLAIMED."

20 AND SO THEY ARE TRYING TO TURN "PRODRUG OF A COMPOUND OF
21 THE INVENTION" TO "PRODRUG THAT IS A COMPOUND OF THE
22 INVENTION."

23 THE COURT: AND SO LET'S TALK ABOUT THIS.

24 THIS KIND OF PATENT IS PARTICULARLY INACCESSIBLE TO
25 SOMEONE WITH MY EDUCATION AND TRAINING BECAUSE THERE ARE VERY

1 FEW ENGLISH WORDS IN IT, AND I CAN ONLY READ ENGLISH WORDS.

2 SO I JUST, I DO NOT KNOW HOW ELSE TO SAY IT, BUT AS HARD
3 AS A SOFTWARE PATENT MIGHT BE OR A PATENT OF A DEVICE, IT'S
4 WRITTEN IN ENGLISH, AND I CAN STUDY THE WORDS. I CANNOT READ
5 THIS PATENT. IT'S NOT ACCESSIBLE TO ME.

6 AND SO WHEN I LOOK AT THIS, I DON'T KNOW WHETHER ANY
7 PRODRUGS ARE EXPRESSLY CLAIMED IN THIS PATENT. AND I CAN ONLY
8 EVALUATE THAT GENERALLY A PATENT IS GOING TO GIVE EXAMPLES
9 WHICH ARE NOT LIMITATIONS. I MEAN, I KNOW THE GENERAL LAW,
10 BUT -- SO HELP ME THROUGH THIS.

11 YOUR ARGUMENT IS THAT THERE IS NOTHING IN THIS PATENT
12 THAT LIMITS THE PRODRUGS THAT ARE ELIGIBLE TO BE COVERED UNDER
13 THIS PATENT IF THEY FULFILL THE REMAINDER OF THE REQUIREMENTS
14 OF THE PATENT.

15 MR. RABINOWITZ: WITH ONE SLIGHT MODIFICATION.

16 THE METHOD OF TREATMENT CAN BE CARRIED OUT BY PROVIDING
17 ANY PRODRUG THAT CONVERTS TO A COMPOUND OF THE INVENTION.

18 AGAIN, THIS CLAIM DOESN'T COVER PRODRUGS THEMSELVES. SO
19 THIS IS NOT AN INVENTION WHICH SAYS WE HAVE FOUND ALL THESE
20 PRODRUGS AND WE ARE PATENTING THEM.

21 THIS PATENT SAYS WE'VE FOUND THE STRUCTURAL FEATURES THAT
22 DISTINGUISH CERTAIN COMPOUNDS THAT ARE USEFUL FOR TREATING
23 HEPATITIS C VIRUS INFECTION, AND WE ARE NOW TEACHING THE WORLD
24 AND CLAIMING, A METHOD OF TREATING HEPATITIS C VIRUS INFECTIONS
25 BY PROVIDING COMPOUNDS WITH THOSE FEATURES, AND YOU CAN CARRY

1 THAT OUT EITHER BY PROVIDING THE COMPOUNDS THEMSELVES OR BY
2 USING A PRODRUG STRATEGY.

3 AND PRODRUGS WERE WELL KNOWN AT THE TIME. THERE ARE
4 REFERENCES INCORPORATED IN THE PATENT, AND THE LAW IS ANYTHING
5 INCORPORATED BY REFERENCE IN THE SPECIFICATION IS AS GOOD AS
6 STATED EXPRESSLY THERE, BUT TO AVOID A HUNDRED OR THOUSAND PAGE
7 SPECIFICATION, WE RELY ON INCORPORATION.

8 AND IN FACT, THE TYPES OF -- THE PARTICULAR TYPES OF
9 PRODRUG, THAT SOFOSBUVIR IS ALSO WELL KNOWN. SO PEOPLE KNEW
10 HOW TO DO THIS.

11 I THINK THAT GILEAD WILL, AND HAS IN THE CONTENTIONS THAT
12 THEY HAVE SERVED ON US, RAISED ISSUES OF ENABLEMENT AND SO ON,
13 THOSE ARE VALIDITY QUESTIONS THAT EVENTUALLY WILL HAVE TO BE
14 DECIDED BY THE JURY.

15 THE COURT: YES.

16 MR. RABINOWITZ: BECAUSE THEY WILL BE DISPUTED.

17 THIS IS NOT SOMETHING THAT THE COURT SHOULD NOW OR NEED
18 EVER DECIDE, I'M HAPPY TO SAY.

19 THE COURT: WELL, I HOPE YOU REMEMBER THAT WHEN IT
20 COMES TIME FOR SUMMARY JUDGEMENT, AND WHEN FILING FIVE BOXES OF
21 MATERIALS ON A USELESS MOTION.

22 MR. RABINOWITZ: THAT'S WHY I EXPRESSLY USE THE WORD
23 DECIDE.

24 I THINK THE COURT MAY NEED TO RECOGNIZE THAT THERE'S A
25 DISPUTE AND THAT THE DISPUTE IS A FACTUAL DISPUTE.

1 THE COURT: WELL, IT'S A TANGENT, NEVERMIND. YOU
2 DON'T NEED MY RANT ON THAT TODAY.

3 MR. RABINOWITZ: BUT IN TERMS -- SO I DON'T THINK THE
4 COURT NEEDS TO UNDERSTAND ANY INTRICACIES OF CHEMISTRY EXCEPT
5 OF NOTION OF A PRODRUG OF A COMPOUND.

6 SO IF THE CLAIM SAYS YOU CAN CARRY THIS METHOD OUT BY
7 PROVIDING A PRODRUG THAT CONVERTS TO A COMPOUND OF THE
8 INVENTION, IF THE PRODRUGS OF A COMPOUND IS LIMITED TO PRODRUGS
9 WHICH ARE COMPOUNDS OF THE INVENTION, IT COLLAPSES THOSE TWO
10 IDEAS.

11 THE COURT: I SEE.

12 MR. RABINOWITZ: AND THAT'S WHAT THEY ARE TRYING TO
13 DO. THEY ARE TRYING TO SAY PROVIDING A PRODRUG THAT IS A
14 COMPOUND OF THE INVENTION, IN OTHER WORDS, A CLAIMED COMPOUND.

15 AND IF YOU LIMIT IT TO PRODRUGS THAT ARE COMPOUNDS OF THE
16 INVENTION, THEN THAT'S THE FIRST PART OF THE DEFINITION.
17 THAT'S ALREADY COVERED AND WOULD MAKE THE SECOND PART
18 EXTRANEOUS.

19 THE COURT: WELL, THAT'S NOT EXACTLY WHAT THIS SAYS.

20 MR. MCCANN WILL HELP ME ON THIS, BUT WHAT GILEAD IS
21 WRITING IS THAT PRODRUG OF A COMPOUND MEANS THOSE PRODRUGS THAT
22 ARE EXPRESSLY CLAIMED.

23 AND WHAT HE ARGUES IS THAT THERE IS A DEFINED CATEGORY OR
24 GROUP OF PRODRUGS THAT HAVE BEEN EXPRESSLY CLAIMED IN THIS
25 PATENT AND IT IS NOT THE ENTIRE UNIVERSE OF PRODRUGS THAT CAN

1 BE TRANSFORMED INTO A COMPOUND OF THE INVENTION.

2 SO I THINK HE'S, WHAT HE'S SUGGESTING IS THAT YOU HAVE IN
3 THIS PATENT, ONLY PROTECTED A SUBSET OF PRODRUGS.

4 MR. RABINOWITZ: SO I THINK WE NEED TO DISTINGUISH
5 SHARPLY BETWEEN DISCLOSED AND CLAIMED.

6 THE COURT: YES.

7 MR. RABINOWITZ: THERE ARE CERTAIN EXAMPLES IN THE
8 PATENT OF THINGS THAT ARE PRODRUGS. AND THE STRUCTURAL FORMULA
9 IN CLAIM 1 OF THE '499 PATENT DOES INCLUDE SOME THINGS WHICH
10 ARE PRODRUGS, BUT THOSE ARE COMPOUNDS OF THE INVENTION.

11 IN OTHER WORDS, COMPOUNDS IS USED AS CLAIMED. IF YOU
12 SIMPLY ELIMINATED THE SECOND PART OF THE DEFINITION IN THE
13 SPECIFICATION AND READ IS IT AS, ADMINISTERING A COMPOUND
14 SHOULD BE UNDERSTOOD TO MEAN PROVIDING A COMPOUND OF THE
15 INVENTION, THAT WOULD COVER THOSE CLAIMED, THOSE PRODRUGS WHICH
16 ARE IN THE FORMULA. THE SECOND PART HAS TO ADD SOMETHING MORE
17 OR IT'S REDUNDANT.

18 AND THAT'S A STRONG PRINCIPLE THE INVENTORS SATISFIED THE
19 SECOND WAY OF SATISFYING ADMINISTERING TO INCLUDE SOMETHING
20 MORE, OTHERWISE WE ARE STRIKING THAT OUT OF THE CLAIM BY
21 READING IT TO BE COTERMINOUS WITH PROVIDING A COMPOUND OF THE
22 INVENTION.

23 THE COURT: BECAUSE YOU ARE SAYING NO PRODRUGS ARE
24 EXPRESSLY CLAIMED?

25 MR. RABINOWITZ: NO, I'M SAYING SOME COMPOUNDS OF THE

1 INVENTION ARE PRODRUGS.

2 THE COURT: SOME COMPOUNDS OF THE INVENTION ARE
3 PRODRUGS?

4 MR. RABINOWITZ: STRUCTURAL FORMULA THAT APPEARS IN
5 CLAIM 1 INCLUDES SOME COMPOUNDS THAT ARE PRODRUGS.

6 THE COURT: AND THOSE ARE BY EXAMPLE ONLY IN YOUR --

7 MR. RABINOWITZ: NO, THEY ARE WITHIN THE STRUCTURAL
8 FORMULA IN THE CLAIM, AND THEREFORE THEY ARE COMPOUNDS THE OF
9 THE INVENTION IN THIS DEFINITION.

10 THE COURT: BUT IT IS NOT EXCLUSIVE.

11 MR. RABINOWITZ: SO WHAT I'M SAYING IS THAT THIS
12 DEFINITION HAS TWO PARTS.

13 NUMBER ONE, YOU CAN PROVIDE A COMPOUND OF THE INVENTION.

14 THE COURT: AND THAT COMPOUND CAN BE A PRODRUG OR A
15 DRUG.

16 MR. RABINOWITZ: YES.

17 THE COURT: I SEE.

18 MR. RABINOWITZ: AND YOU CAN HAVE A PRODRUG OF A
19 PRODRUG.

20 IN FACT, THE DIAGRAM I WILL SHOW YOU IN A SECOND SHOWS
21 THAT SOFOSBUVIR ITSELF CONVERTS INTO A MONOPHOSPHATE WHICH IS
22 INACTIVE, THEN A DIPHOSPHATE WHICH ISN'T ACTIVE, THEN A
23 TRIPHOSPHATE WHICH ISN'T ACTIVE, WHICH IS THE ACTIVE PART.

24 SO THERE'S --

25 THE COURT: THAT'S SOMETHING I HADN'T THOUGHT OF, THE

1 MONO AND DI AS BEING PRODRUGS THEMSELVES.

2 MR. RABINOWITZ: THEY ARE COMPOUNDS. IF YOU LOOK AT
3 THE DEFINITIONS, THEY ARE COMPOUNDS THAT HAVE TO BE CONVERTED
4 TO SOMETHING ELSE TO MAKE, TO EXERT THEIR PHARMACOLOGICAL
5 ACTION.

6 THE COURT: OKAY.

7 MR. RABINOWITZ: AND YOU CAN HAVE MORE COMPLICATED
8 PRODRUGS, YOU CAN PUT IN, ADD VARIOUS MOIETIES, VARIOUS
9 CHEMICAL GROUPS.

10 THE COURT: SO YOU ARE TELLING ME THAT COMPOUND OF
11 THE INVENTION IS NOT SYNONYMOUS WITH THE DRUG OF THE INVENTION.

12 MR. RABINOWITZ: I'M SAYING -- THAT'S RIGHT.
13 BECAUSE --

14 THE COURT: DRUG MEANING SOMETHING THAT'S ACTIVE.

15 MR. RABINOWITZ: BECAUSE THERE ARE SOME COMPOUNDS OF
16 THE INVENTION WHICH ARE PRODRUGS AND NEED CONVERSION TO EXERT
17 THEIR ACTIVITY.

18 AND IN FACT, THAT FORMULA INCLUDES MONO AND DIPHOSPHATE
19 COMPOUNDS WHICH ARE NOT PHARMACOLOGICALLY ACTIVE UNTIL THEY
20 HAVE BEEN CONVERTED INTO TRIPHOSPHATES.

21 THE COURT: ALL RIGHT. LET ME JUST BE SURE.

22 WELL, IF COMPOUND OF THE INVENTION IS BROAD ENOUGH TO
23 INCORPORATE BOTH ACTIVE DRUGS AND PRODRUGS --

24 MR. RABINOWITZ: COMPOUNDS OF THE INVENTION MEANS
25 COMPOUNDS WHOSE STRUCTURE FITS WITHIN THE FORMULA IN CLAIM 1.

1 SO YOUR HONOR, I'M NOT SURE IF YOU HAVE A COPY OF THE
2 PATENT AVAILABLE TO YOU, WE CAN PROVIDE ONE.

3 THE COURT: I HAVE IT RIGHT HERE.

4 MR. RABINOWITZ: OKAY. IF WE GO TO COLUMN 137.

5 THE COURT: HOLD ON, LET ME JUST CATCH UP WITH YOU.

6 MR. RABINOWITZ: SO IT HAS THAT STRUCTURAL FORMULA
7 III.

8 I DON'T THINK WE NEED TO GET INTO THE DETAILS, BUT THE
9 PRINCIPLES OF IT IS AS PROFESSOR WUEST SHOWED YOU LAST WEEK, IT
10 PREDICTS THE ARRANGEMENTS AND HOW ATOMS ARE CONNECTED TO EACH
11 OTHER. IT HAS OPTIONS, SOMETHING WHICH MR. MCCANN EXPLAINED
12 LAST WEEK AS WELL. THAT DEFINES A CLASS OF COMPOUNDS, SOME OF
13 WHICH ARE PRODRUGS AND MOST OF WHICH ARE NOT.

14 THOSE ARE THE COMPOUNDS OF THE INVENTION FOR PURPOSES OF
15 CLAIM 1.

16 THE COURT: SO A COMPOUND OF THE INVENTION HAS SOME
17 DRUGS AND SOME PRODRUGS.

18 MR. RABINOWITZ: ACTUALLY, IT HAS -- IT INCLUDES
19 THINGS WHICH ARE TRIPHOSPHATES AND THINGS WHICH ARE NOT. SO IT
20 HAS SOME THINGS WHICH ARE --

21 THE COURT: WOULD YOU RATHER SAY ACTIVE AND INACTIVE?

22 MR. RABINOWITZ: YEAH.

23 IT'S NOT USUAL IN PATENT CLAIMS TO DISTINGUISH BETWEEN
24 THINGS WHICH ARE THEMSELVES ACTIVE DRUGS OR NOT AS LONG AS THEY
25 ARE USEFUL --

1 THE COURT: BECAUSE PRODRUG WE KNOW IS INACTIVE.

2 MR. RABINOWITZ: YES.

3 THE COURT: SO THAT'S WHY I'M TRYING TO, A PRODRUG
4 OF --

5 MR. RABINOWITZ: SO I WOULD AGREE WITH YOU.

6 THIS INCLUDES COMPOUNDS WHICH ARE THEMSELVES DIRECTLY
7 ACTIVE AND OTHER COMPOUNDS WHICH CONVERT TO ACTIVE COMPOUNDS.

8 THE COURT: BECAUSE BY THAT DEFINITION, THE SECOND
9 PHRASE OF YOUR DEFINITION IS SUPERFLUOUS BECAUSE THE FIRST ONE
10 IS BROAD ENOUGH TO INCLUDE BOTH, SO I'M JUST CONFUSED.

11 IF A COMPOUND OF THE INVENTION INCLUDES BOTH PRODRUGS AND
12 DRUGS THAT ARE ACTIVE AND INACTIVE OR A PRODRUG OF --

13 MR. RABINOWITZ: SO LET ME GIVE YOU A CONCRETE
14 EXAMPLE TO TRY TO CLARIFY THAT.

15 LET'S IMAGINE WE WERE TALKING ABOUT SALICYLIC ACID.
16 LET'S IMAGINE THAT THIS FORMULA INCLUDED ASPIRIN AND SALICYLIC
17 ACID BUT NOT OTHER PRODRUGS OF SALICYLIC ACID.

18 PROVIDING A COMPOUND OF THE INVENTION WOULD COVER
19 PROVIDING SALICYLIC ACID OR PROVIDING ASPIRIN EVEN
20 THOUGH ASPIRIN IS A --

21 THE COURT: EXPRESSLY.

22 MR. RABINOWITZ: YES.

23 THE COURT: OKAY.

24 MR. RABINOWITZ: BUT IF IT SAYS OR PROVIDING A
25 PRODRUG OF A COMPOUND OF THE INVENTION, THAT INCLUDES OTHER

1 PRODRUGS OF SALICYLIC ACID.

2 THE COURT: OTHER THAN ASPIRIN.

3 MR. RABINOWITZ: OTHER THAN ASPIRIN.

4 THE COURT: OH, I SEE.

5 MR. RABINOWITZ: AND SO BY SAYING THE ONLY PRODRUGS
6 OF THE COMPOUNDS ARE THOSE THAT ARE EXPRESSLY CLAIMED, THEY ARE
7 COLLAPSING THOSE TWO THINGS INTO ONE.

8 THE COURT: I UNDERSTAND. I THINK IT'S VERY BROAD.
9 I DON'T KNOW HOW THAT HOLDS UP LATER, BUT THAT'S NOT MY CONCERN
10 TODAY.

11 MR. RABINOWITZ: THAT'S EXACTLY RIGHT, YOUR HONOR.

12 THE COURT: IT WILL BE MY CONCERN, I RECOGNIZE.
13 OKAY. ALL RIGHT.

14 MR. RABINOWITZ: SO THAT'S WHY WE SAY IT'S
15 EFFECTIVELY A REWRITE THAT EVISCERATES THE SECOND PART OF THE
16 DEFINITION OF "ADMINISTERING" BY MAKING "PRODRUG OF A COMPOUND
17 OF THE INVENTION" SYNONYMOUS WITH COMPOUNDS OF THE INVENTION
18 THAT HAPPEN TO BE PRODRUGS.

19 THEN THIS IS REALLY TO SET IT IN CONTEXT, BUT I THINK
20 FROM YOUR HONOR'S QUESTIONS YOU HAVE IT IN MIND.

21 THE CENTRAL PORTION OF THIS DIAGRAM IS TAKEN FROM
22 GILEAD'S OWN BRIEF. SOME OF THE STEPS ARE OMITTED, THERE ARE
23 MORE STEPS OVER HERE, AND IT ACTUALLY DOESN'T MATTER HOW MANY
24 STEPS THE PRODRUG HAS TO GO THROUGH TO BECOME THE ACTIVE DRUG,
25 THE BODY DOES THAT. BUT IT GOES THROUGH SOME STEPS BEFORE IT

1 BECOMES THE MONOPHOSPHATE THEN THE DIPHOSPHATE, EACH OF WHICH
2 IS INACTIVE BUT THEY ARE COMPOUNDS OF THE INVENTION.

3 THE COURT: IT SEEMS LIKE EACH OF THOSE STEPS IN
4 ITSELF IS A PRODRUG. EACH TRANSFORMATION YOU COULD HAVE
5 VIRTUALLY AN INFINITE NUMBER OF PRODRUGS.

6 MR. RABINOWITZ: HAPPENS ALL THE TIME. THINGS GET
7 METABOLIZED IN MULTIPLE STEPS UNTIL THEY BECOME ACTIVE AGENTS.

8 AND WHAT ONE DOES IN THE PRODRUG STRATEGY IS YOU USE THE
9 BODY'S EXISTING MACHINERY TO CONVERT THE PRODRUG INTO THE
10 ACTIVE AGENT. AND THIS IS PREDICTABLE, IT'S KNOWN, THESE TYPES
11 OF PHOSPHOROUS PRODRUGS WERE PUBLISHED --

12 THE COURT: WHAT YOU ARE REALLY SAYING IS THAT ANY
13 PRODRUG THAT LIGHTS UP THE ROUTE TO THE TRIPHOSPHATE THAT IS
14 THE COMPOUND OF THIS INVENTION IS PATENTED.

15 MR. RABINOWITZ: NO.

16 THE PRODRUG ISN'T PATENTED BUT THE METHOD OF TREATMENT
17 THAT IS PATENTED CAN BE PERFORMED BY ADMINISTERING A PRODRUG.

18 THE COURT: OKAY.

19 MR. RABINOWITZ: AGAIN, IF THE PRODRUG TREATS CANCER,
20 YOU KNOW, IT'S DIFFERENT.

21 SO THERE'S A BIG DIFFERENCE BETWEEN PATENTING A PRODRUG
22 AND PATENTING A METHOD OF TREATMENT THAT CAN BE CARRIED OUT
23 USING A PRODRUG STRATEGY. THE PRODRUG IN THE METHOD OF
24 TREATMENT IS REALLY A DELIVERY DEVICE.

25 THE COURT: ALL RIGHT.

1 SO THEN, SO THAT I UNDERSTAND THIS, ANY PRODRUG THAT
2 LIGHTS UP THIS ROUTE TO TRIPHOSPHATE, FOR THE PURPOSE OF
3 TREATING HEPATITIS C, IS COVERED.

4 MR. RABINOWITZ: IF A PATIENT IS TREATED BY
5 ADMINISTERING SOME PRODRUG THAT CONVERTS TO A TRIPHOSPHATE OF
6 THE COMPOUNDS OF THIS CLASS, DEFINED BY THE FORMULA, THEN THAT
7 WILL BE A PERFORMANCE OF THE METHOD CARRYING OUT OF THIS
8 CLAIMED METHOD, YES.

9 THE COURT: WELL, I GUESS WE WILL GET TO PREEMPTION
10 ISSUES LATER.

11 OKAY.

12 MR. RABINOWITZ: SO I JUST WANT TO ADDRESS SOME OF
13 THE ARGUMENTS THAT GILEAD RAISED IN ITS OPPOSITION BRIEF,
14 AGAIN, TO OUR PROPOSED CONSTRUCTION.

15 ONE IS "IN COMBINATION WITH," WE SPOKE ABOUT THAT
16 ALREADY.

17 THE COURT: YES.

18 MR. RABINOWITZ: AS LONG AS THE PATIENT RECEIVES TWO
19 THERAPEUTIC AGENTS DURING THE COURSE OF THERAPY.

20 WE ACTUALLY, I DON'T UNDERSTAND HOW THAT IN ANY WAY
21 CONSTRAINS WHETHER YOU PERFORM THE SOFOSBUVIR PART BY GIVING,
22 YOU KNOW, THE TRIPHOSPHATE OR GIVING THE PRODRUG, IT HAS NO
23 BEARING WHETHER YOU GIVE A SECOND AGENT OR NOT.

24 AND THIS IS THE LABEL FOR SOFOSBUVIR, THIS IS GIVEN BY
25 GILEAD IN SUPPORT OF THEIR OPPOSITION.

1 YOU CAN SEE THAT SOVALDI, WHICH IS THE FIRST DRUG THAT
2 CONTAINS SOFOSBUVIR, IS USED IN COMBINATION WITH RIBAVIRIN.
3 THAT'S ANOTHER TABLET, DOESN'T SAY WHETHER YOU HAVE TO SWALLOW
4 IT AT THE SAME TIME OR SEPARATELY, OR PEGYLATED INTERFERON
5 WHICH IS ACTUALLY A DRUG GIVEN BY INJECTION.

6 THE COURT: WHICH IS THE TRADITIONAL THERAPY.

7 MR. RABINOWITZ: YES. IT'S PART OF THE -- AND IN
8 FACT, USED WITH SOVALDI AS WELL FOR CERTAIN TYPES OF HEP C
9 INFECTIONS.

10 THE COURT: I REALIZE THAT WAS STILL PART OF THE
11 TREATMENT, THAT'S UNFORTUNATE.

12 MR. RABINOWITZ: YOU KNOW, IT'S A TOUGH DISEASE TO
13 TREAT AND SOME OF THE GENOTYPES ARE MORE RESISTANT THAN OTHERS
14 TO THERAPY.

15 AND YOU KNOW, MERCK AND OTHERS ARE WORKING TO DEVELOP
16 IMPROVED COMBINATION THERAPIES THAT MAY ELIMINATE THAT.

17 THE EXTRINSIC EVIDENCE ARGUMENT I THINK WE HAVE
18 ADDRESSED, THE MERCK MANUAL IS AN EXCELLENT SOURCE, BUT IT'S
19 NOT INCORPORATED BY REFERENCE.

20 THE COURT: NO, IT'S NOT, BUT IT'S INTERESTING.

21 MR. RABINOWITZ: AND INCIDENTALLY, THE MERCK MANUAL
22 EVEN IF IT WERE CONSIDERED, SUPPORT THE PROPOSITION THAT YOU
23 CAN IGNORE METABOLISM BECAUSE IT EXPRESSLY SAYS YOU HAVE TO
24 TAKE IT.

25 THE COURT: IF I ACCEPT THIS AS A DEFINITION, AND HAD

1 THAT NOT BEEN THERE THEN THE MERCK MANUAL WOULD HAVE BEEN
2 VALUABLE.

3 MR. RABINOWITZ: THEN WE WOULD HAVE ARGUED WHETHER
4 IT'S SUPPORTED IN THE DEFINITION OR NOT.

5 THE COURT: SURE.

6 MR. RABINOWITZ: AND THEN WE GET TO THE PROSECUTION
7 HISTORY ARGUMENT.

8 THE COURT: YEAH.

9 MR. RABINOWITZ: BECAUSE I THINK IT'S IMPORTANT TO
10 UNDERSTAND IN ORDER TO DISMISS IT.

11 SO I JUST WANT TO DISTINGUISH FOR THE COURT, GILEAD WAS
12 QUITE CORRECT IN CALLING IT A PROSECUTION DISCLAIMER. THERE'S
13 ANOTHER DOCTRINE WHICH HAS A SIMILAR NAME CALLED PROSECUTION
14 HISTORY ESTOPPEL. THAT'S NOT WHAT WE ARE TALKING ABOUT.

15 PROSECUTION HISTORY ESTOPPEL IS EASILY TRIGGERED BY ANY
16 NARROWING AMENDMENT TO THE CLAIMS OR EVEN ARGUMENTS MADE IN
17 SUPPORT OF PATENTABILITY, BUT IT DOESN'T AFFECT THE LITERAL
18 SCOPE OF THE CLAIM. IT ONLY LIMITS THE EXTENT TO WHICH YOU CAN
19 EXPAND THE LITERAL SCOPE OF THE CLAIM BY REFERENCE TO THE
20 DOCTRINE OF EQUIVALENT. WE ARE NOT TALKING ABOUT THAT HERE.

21 THE COURT: AND YOU BOTH AGREE, SO THAT'S JUST A GOOD
22 DISTINCTION.

23 MR. RABINOWITZ: YES.

24 WHAT WE ARE TALKING ABOUT IS ANOTHER DOCTRINE CALLED
25 PROSECUTION DISCLAIMER. AND THE RARELY HAPPENS, THE

1 REQUIREMENTS ARE EXTREMELY EXACTING. AND WHAT IT DOES IS IT
2 NARROWS THE LITERAL SCOPE OF THE CLAIM.

3 THE COURT: I SEE.

4 MR. RABINOWITZ: AND THAT'S THE DOCTRINE THAT GILEAD
5 IS ADVERTING TO NOW.

6 AND SO THE OMEGA ENGINEERING CASE ACTUALLY EXPLAINS HOW
7 DIFFICULT, IT MUST BE UNAMBIGUOUS, IT MUST BE A CLEAR
8 UNAMBIGUOUS DISCLAIMER. IF THERE'S ANY AMBIGUITY, IF THERE ARE
9 DIFFERENT LEGITIMATE WAYS OF INTERPRETING THE EXCHANGE BETWEEN
10 THE APPLICANT AND THE EXAMINER, IT DOES NOT, IT CANNOT WORK TO
11 EFFECT A DISAVOW OF CLAIM SCOPE.

12 AND THOSE ARE THE QUOTATIONS FROM OMEGA ENGINEERING THAT
13 WE HAVE PROVIDED.

14 THE COURT: YES.

15 MR. RABINOWITZ: AND SO LET'S LOOK AT THE ENTIRETY OF
16 THE EXCHANGE ON THIS POINT BETWEEN THE EXAMINER AND THE
17 APPLICANT.

18 AND SO THIS IS TAKEN FROM THE SUBMISSION THAT GILEAD
19 PROVIDED IN SUPPORT OF ITS OPPOSITION, THE RESPONSIVE BRIEF.

20 THIS WAS, AT THE TIME, NEW CLAIM 53 WHICH BECAME AN
21 AMENDED FORM CLAIM 1 OF THE '499 PATENT. AND AT THAT TIME IT
22 HAD THE SAME WORDS EXCEPT THAT IT SAID "OR A PHARMACEUTICALLY
23 ACCEPTABLE SALT OR ESTER PRODRUG THEREOF." AND THIS WAS
24 CHANGED IN WHAT'S CALLED AN EXAMINER'S AMENDMENT, USUALLY
25 AMENDMENTS ARE MADE BY THE APPLICANTS SUBMITTED TO THE EXAMINER

1 AND THE EXAMINER ENTERS THEM OR NOT.

2 AN EXAMINER'S AMENDMENT IS THE LAST THING THAT HAPPENS
3 WHEN THE EXAMINER SAYS, I'M PREPARED TO ALLOW THE CLAIM IF YOU
4 WILL AUTHORIZE ME, THE EXAMINER, TO MAKE THE AMENDMENT.

5 SO THIS WAS DONE CONCURRENTLY. AND NORMALLY IF THE
6 EXAMINER SAYS I'M REJECTING YOUR CLAIM FOR THIS REASON, YOU
7 KNOW WHY, AND THE APPLICANT THEN HAS 3 TO 6 MONTHS, DEPENDING
8 ON THE EXTENSIONS, TO RESPOND, EXPLAIN WHY IT'S BEING AMENDED,
9 WHAT'S BEING DONE WITH THE AMENDMENTS, SO YOU HAVE A RECORD.

10 BECAUSE IT WAS DONE IN THE EXAMINER'S AMENDMENT, THERE'S
11 NO RECORD OF WHY THE AMENDMENT WAS AS CORRECTED BY THE EXAMINER
12 OR AGREED TO BY THE APPLICANT.

13 AND I WILL SUBMIT THAT THERE'S AN EXCELLENT REASON WHY
14 THE EXAMINER SHOULD HAVE REQUIRED THIS AMENDMENT, AND THAT IS
15 BECAUSE THE WORD "ADMINISTERING" IN THE CLAIM ALREADY INCLUDES
16 PRODRUGS THAT CONVERT TO THE COMPOUNDS OF THE INVENTION. AND
17 TO SAY, OR ESTER PRODRUG THEREOF, IS REDUNDANT AND CONFUSING.

18 AND SO AS WE SUBMITTED IN OUR REPLY BRIEF, WHAT WE THINK
19 WENT ON IS THAT THE EXAMINER ELIMINATED THE CONFUSION BY MAKING
20 THE EXAMINER'S AMENDMENT TO THE CLAIM WITH THE APPROVAL OF THE
21 APPLICANT'S ATTORNEY.

22 THE COURT: BUT HE SUBSTITUTED ACYL DERIVATIVES.

23 MR. RABINOWITZ: YES. ACYL DERIVATIVES IS NOT
24 REDUNDANT BECAUSE ACYL DERIVATIVES ARE NOT SYNONYMOUS WITH THE
25 SUBCLASS OF PRODRUGS.

1 THE COURT: BUT IT MUST HAVE HAD SOME RELATIONSHIP TO
2 ESTER PRODRUG.

3 MR. RABINOWITZ: NO.

4 THE SUBSTITUTED PHRASE HAD NO RELATIONSHIP TO THE PHRASE
5 AT ALL. AND SO THERE IS NO, AS OMEGA ENGINEERING SAID, THIS
6 SPARSE HISTORY PROVIDES NO BASIS FOR PROSECUTION DISCLAIMER.

7 THIS IS ABOUT AS AMBIGUOUS AS IT GETS. IT CERTAINLY IS
8 NOT THE UNEQUIVOCAL DISAVOWAL OF CLAIM SCOPE, PARTICULARLY NOT
9 DISAVOWAL OF PRODRUGS THAT ARE PART OF THE DEFINITION THAT
10 WOULD BE REQUIRED TO INVOKE THE DOCTRINE OF PROSECUTION
11 DISCLAIMER.

12 AND THEN FINALLY, AND I THINK YOUR HONOR IS THERE, WE
13 SUBMIT THAT GILEAD'S INVALIDITY ARGUMENTS OUGHT NOT TO PLAY ANY
14 PART IN THIS. WE REGARD THEM AS MERITLESS.

15 JUST TO PUT IT BLUNTLY, GILEAD IS NO FRIEND OF THESE
16 CLAIMS IN THE SUMMARY JUDGEMENT ACTION.

17 MR. MCCANN: WE WILL STIPULATE TO THAT, YOUR HONOR.

18 THE COURT: THAT WAS ONE OF THOSE ARGUMENTS IN THE
19 BRIEF I WAS PROBABLY GOING TO IGNORE AND NOT EVEN ADDRESS.

20 I JUST -- WE WILL GET TO THAT. AND SO BE IT, IF WHAT YOU
21 WANT NOW CAUSES INVALIDITY LATER, THEN THAT'S THE WAY IT GOES.

22 MR. RABINOWITZ: WE WILL DEAL WITH THAT BEFORE THE
23 RIGHTS FINDER OF FACTS FOR ANY ARGUMENTS WHICH ARE ADVANCED.

24 WE HAVE THE PRESUMPTION OF VALIDITY, WE HAVE CLEAR AND
25 CONVINCING BURDEN OF EVIDENCE, WE HAVE THE JURY WHICH IS THE

1 FINDER OF ANY FACTS WHICH ARE NECESSARY, WE HAVE HERE ZERO
2 EVIDENCE BEFORE THIS COURT NOW OF INVALIDITY AND AN ALLEGATION
3 OF INVALIDITY.

4 THE COURT: YES.

5 AND IF YOUR REQUESTED CONSTRUCTION CAUSES YOU TO LOSE IN
6 THAT NEXT PROCEEDING BEFORE THE JURY, THEN SO BE IT.

7 MR. RABINOWITZ: WE WILL VIGOROUSLY DENY AND DISPUTE
8 THAT THE CLAIMS ARE ALLEGEDLY INVALID, BUT TO CARVE OUT WHAT IS
9 WITHIN THE DEFINITION IN THE SPECIFICATION FOR FEAR THAT THERE
10 MIGHT BE INVALIDITY IS TO --

11 THE COURT: NO, THAT'S NOT MY CONCERN.

12 MR. RABINOWITZ: -- IS TO DO AN END RUN AROUND THE
13 PRESUMPTION AND INVALIDITY OF PROOF.

14 THE COURT: ALL RIGHT. WE CAN MOVE ON FROM THIS
15 ARGUMENT.

16 MR. RABINOWITZ: THEN YOUR HONOR, I JUST WANTED TO
17 SAY A FEW WORDS ABOUT THE PATENT SYSTEM BECAUSE IT RELATES TO
18 THE POLICY ARGUMENTS WE HEARD IN THE PRESENTATION LAST WEEK AND
19 I SUSPECT ARE GOING TO BE ADVANCED AGAIN WHEN I SIT DOWN.

20 AND THE PATENT SYSTEM, OUR PATENT SYSTEM STIMULATES
21 INNOVATION TWO WAYS.

22 THE FIRST IS OBVIOUS, IT ENCOURAGES PEOPLE TO MAKE
23 INVENTIONS AND DISCLOSE THEM TO THE PUBLIC. IN EXCHANGE FOR A
24 PATENT WHICH GIVES THE INVENTORS THE RIGHT TO EXCLUDE OTHERS
25 FROM PRACTICING THEIR INVENTION DURING THE LIFE OF THE PATENT,

1 WHICH BY STATUTE NOW IS 20 YEARS FROM APPLICATION. SO MOST
2 PEOPLE KNOW THAT.

3 THERE'S A SECOND WAY IN WHICH THE PATENT SYSTEM
4 ENCOURAGES INNOVATION, AND THAT IS DISCLOSURE OF INVENTIONS IN
5 PATENTS OR PATENT APPLICATIONS. AND THE PATENT OFFICE NOW
6 PUBLISHES PATENT APPLICATIONS AFTER 18 MONTHS FOR THIS REASON,
7 THIS POLICY REASON, IT WAS WRITTEN IN THE STATUTE. IT
8 ENCOURAGES PEOPLE TO MAKE FOLLOW-ON INVENTIONS.

9 AGAIN, FOR WHICH THEY CAN RECEIVE A PATENT WHICH HAS ITS
10 OWN 20-YEAR TERM WHICH STARTS LATER AND ENDS LATER.

11 AFTER THE PATENTS EXPIRE, THE PATENT SUBJECT MATTER
12 BECOMES -- GOES INTO THE PUBLIC DOMAIN AND CAN BE USED WITHOUT
13 TRIBUTE.

14 AND TYPICALLY THE FIRST PATENT IS BROADER, IT'S OFTEN THE
15 FUNDAMENTAL INVENTION. THE SECOND, THE FOLLOW-ON INVENTION, IS
16 OFTEN A SELECTION THAT SOMEONE HAS FOUND THE BEST WAY OF
17 CARRYING OUT THE FOUNDATIONAL INVENTION OR AN IMPROVEMENT.
18 THEY HAVE FOUND A BETTER WAY OF CARRYING OUT THE FOUNDATION
19 INVENTION.

20 SO IF I INVENT THE BICYCLE AND YOU PUT A MOTOR ON IT AND
21 MAKE IT A MOTOR BIKE, WHILE MY BICYCLE PATENT IS ENFORCED, YOU
22 CAN'T COMMERCIALIZE MAKING USE WITH MOTOR BIKES WITHOUT A
23 LICENSE FROM ME BECAUSE IT'S AN IMPROVEMENT ON THE BICYCLE.

24 BUT ONCE THE BICYCLE PATENT EXPIRES AND THE BICYCLES ARE
25 IN THE PUBLIC DOMAIN, THEN THERE'S ONLY THE MOTOR BIKE PATENT

1 UNTIL IT EXPIRES, THEN THE PUBLIC HAS ALL OF IT FREE OF CHARGE.

2 AND THESE ARE OFTEN CALLED DOMINANT AND SUBSERVIENT
3 PATENTS BECAUSE THE EARLIER ISSUED PATENT IS OFTEN BROADER AND
4 DOMINATES THE USE OF THE IMPROVEMENT UNTIL IT EXPIRES.

5 THE COURT: SO THE IMPROVEMENT ITSELF GETS A PATENT
6 BUT IT REQUIRES A RESIDENCE LICENSE TO USE ITS PLATFORM.

7 MR. RABINOWITZ: EXACTLY.

8 THE COURT: SO THAT'S WHAT YOU WOULD CONSIDER THIS
9 SITUATION?

10 MR. RABINOWITZ: THAT'S EXACTLY WHAT WE HAVE HERE.

11 THE MERCK AND ISIS SCIENTISTS MADE A FUNDAMENTAL
12 DISCOVERY. THEY DISCOVERED THAT BY ATTACHING CERTAIN CHEMICAL
13 GROUPS TO THESE COMPOUNDS CALLED NUCLEOSIDE ANALOGS, THEY
14 OBTAIN COMPOUNDS THAT INHIBIT AN IMPORTANT ENZYME OF THE
15 HEPATITIS C VIRUS WHICH PROVIDES A METHOD FOR TREATING
16 HEPATITIS C VIRUS INFECTIONS.

17 SOFOSBUVIR IS AN APPLICATION OF THIS FUNDAMENTAL WORK
18 INVENTION. THE REASON WHY SOFOSBUVIR INHIBITS THAT ENZYME OF
19 THE VIRUS, THE REASON WHY SOFOSBUVIR WORKS TO TREAT HEPATITIS C
20 VIRUS INFECTION IS BECAUSE IT CONTAINS A CHEMICAL GROUP CALLED
21 A METHYL GROUP, AT A CERTAIN POSITION OF THE COMPOUND CALLED
22 THE TWO PRIME CARBON. AND THAT'S SOMETHING YOU DID HEAR ABOUT
23 LAST WEEK.

24 WITHOUT THE METHYL GROUP AT THE TWO PRIME CARBON,
25 SOFOSBUVIR WOULDN'T WORK, IT WOULD DO NO GOOD AT ALL. IT WAS

1 MERCK AND ISIS THAT DISCOVERED THAT ATTACHING A METHYL GROUP AT
2 THE TWO PRIME CARBON CREATES A COMPOUND THAT INHIBITS THAT
3 ENZYME. AND THAT ENABLED THEM TO GET CLAIMS TO COMPOUNDS AND
4 METHODS OF TREATING HEPATITIS C VIRUS INFECTION WHICH ARE AT
5 ISSUE IN THIS CASE.

6 AND NO ONE DENIES THAT SOFOSBUVIR IS A USEFUL AND HIGHLY
7 SUCCESSFUL DRUG. THIS COURT DOESN'T HAVE TO DECIDE WHETHER
8 SOFOSBUVIR DESERVES ITS OWN PATENTS OR INDEED WHO IS ENTITLED
9 TO OWN THE PATENTS ON SOFOSBUVIR, THAT QUESTION IS THE SUBJECT
10 OF LITIGATION NOW IN THE DISTRICT OF DELAWARE.

11 WHAT IS AT ISSUE HERE IS WHETHER THE USE OF SOFOSBUVIR
12 USES THE INVENTION WHICH IS PATENTED IN THE PATENTS IN SUIT
13 ASSERTED HERE BY MERCK.

14 THE COURT: IT SEEMS TO UNLOCK THE DOOR TO THIS
15 TREATMENT.

16 MR. RABINOWITZ: THAT'S EXACTLY OUR SUBMISSION.

17 IT WAS A FUNDAMENTAL DISCOVERY AND SOFOSBUVIR WAS AN
18 APPLICATION, PERHAPS AN IMPROVEMENT OF IT. SOFOSBUVIR MAY WELL
19 BE ENTITLED TO ITS OWN PATENTS, WE WOULD DISAGREE WITH GILEAD,
20 RESPECTFULLY, ON WHO OWNS THOSE PATENTS, BUT THAT'S NOT THE
21 SUBJECT OF THIS PROCEEDING.

22 THE COURT: NO.

23 MR. RABINOWITZ: BUT THAT IS IRRELEVANT TO THE
24 QUESTION OF WHETHER THE USE OF SOFOSBUVIR CARRIES OUT THE
25 INVENTION PROTECTED BY THESE MERCK PATENTS IN SUIT HERE.

1 TO ANSWER THAT QUESTION ACCURATELY, WE SUBMIT THE COURT
2 SHOULD GIVE THE TERM ADMINISTERING THE SCOPE THAT IS DEFINED
3 FOR IT IN THE SPECIFICATION OF THESE PATENTS.

4 AND WE BELIEVE THAT MERCK'S CONSTRUCTION IS PROPER, IT'S
5 IDENTICAL TO THE DEFINITION IN THE SPECIFICATION, IT DOES NOT
6 DELETE WORDS EXPRESSLY OR IMPLICITLY FROM THE DEFINITION, IT
7 DOESN'T ADD NEW LIMITATIONS TO THE DEFINITION FOUND IN THE
8 SPECIFICATION, AND IT'S CONSISTENT WITH BASIC SCIENTIFIC
9 PRINCIPLES OF A PRODRUGS THAT WERE EXPLAINED BY DR. WUEST AND
10 THAT ARE UNCONTROVERTED AND ESTABLISHED BY THE ARTICLE OF
11 PROFESSOR STELLAR.

12 THE COURT: THANK YOU, MR. RABINOWITZ.

13 MR. MCCANN, I THINK IT WOULD PROBABLY BE A GOOD IDEA TO
14 TAKE A TEN-MINUTE BREAK SO THAT I DON'T HAVE TO TAKE A BREAK IN
15 THE MIDDLE OF YOUR PRESENTATION.

16 MR. MCCANN: THAT'S FINE, YOUR HONOR.

17 THE COURT: GOOD. THANK YOU. LET'S DO THAT.

18 (WHEREUPON A RECESS WAS TAKEN.)

19 THE COURT: ALL RIGHT. THANK YOU. YOU MAY BE
20 SEATED. ALL RIGHT, MR. MCCANN, WE WILL BE ABLE TO GIVE YOU AN
21 UNINTERRUPTED PRESENTATION AS WELL.

22 MR. MCCANN: THANK YOU, YOUR HONOR.

23 MAY I PROCEED?

24 THE COURT: YES, PLEASE.

25 MR. MCCANN: YOUR HONOR, I THOUGHT I WOULD BEGIN

1 WHERE MR. RABINOWITZ LEFT OFF AND JUST PUT A LITTLE CONTEXT
2 AROUND TODAY'S HEARING.

3 AND MR. RABINOWITZ MADE THE POINT THAT THERE ARE A LOT OF
4 PATENTS THAT ARE FOUNDATIONAL, AND THEY ARE, AS HE PUT IT, ARE
5 OPEN DOORS TO NEW AREAS OF DEVELOPMENT. AND HE SAID THAT MERCK
6 HAD DONE INNOVATIVE WORK IN THIS KIND OF MOLECULE, SPECIFICALLY
7 WITH THAT METHYL AT THE TWO PRIME POSITION.

8 AND WHAT I WOULD LIKE YOUR HONOR TO KEEP IN MIND, I
9 SUPPOSE IS, DO THE CLAIMS THAT MERCK HAS IN ITS PATENT COVER
10 MORE THAN WHAT MERCK INVENTED? IS IT BROADER THAN THE
11 DISCLOSURE OF THAT PATENT?

12 YOUR HONOR RECALLS, I HOPE FROM THE TECH TUTORIAL, THAT
13 SOFOSBUVIR, I HAD BROKEN IT INTO THREE PARTS. I AM NOW
14 REFERRING TO SLIDE 37 FROM THE TECH TUTORIAL.

15 THE COURT: LET ME JUST OPEN THAT UP BECAUSE I HAVE
16 IT RIGHT HERE. YEAH.

17 MR. MCCANN: MR. RABINOWITZ WAS REFERRING YOU TO THE
18 CENTER PIECE WHICH IS CALLED THE SUGAR RING, AND IT HAS THE TWO
19 METHYL UP, AND HE WAS TELLING YOU THIS IS MERCK'S FOUNDATIONAL
20 CONTRIBUTION.

21 BUT MERCK'S PATENT WHICH HAS 154 EXAMPLES OF COMPOUNDS,
22 ALL OF THEM FAILED, NONE OF THEM EVER CAME TO MARKET. MERCK,
23 TO THIS DAY, DOES NOT SELL A DRUG THAT PRACTICES THE '499
24 PATENT.

25 AND WHAT GILEAD DID AND ITS PREDECESSOR PHARMASSET, IT'S

1 NOT JUST A METHYL UP, IT'S ALSO THE FLUORINE DOWN AT THAT SAME
2 POSITION. AND IT'S ALSO THE USE OF THAT PHOSPHORAMIDATES
3 PRODRUG.

4 TODAY WE ARE GOING TO BE FOCUSED ON WHETHER THEIR CLAIM
5 COVERS THIS PRODRUG. BUT MY POINT IS --

6 THE COURT: SO THEY SAY THAT THEIR CLAIM DOESN'T
7 COVER ANY PRODRUGS, PER SE.

8 MR. MCCANN: IT DOES. I'M GOING TO SHOW YOU THAT,
9 YOUR HONOR.

10 YOU ALSO MADE THE POINT THAT THIS PATENT IS QUITE
11 INACCESSIBLE AND NOT MUCH OF IT IS WRITTEN IN ENGLISH. AND I
12 SHOULD TELL YOUR HONOR THAT I WAS A HISTORY MAJOR IN COLLEGE.
13 I WENT TO THE NAVAL ACADEMY AND THAT DID FORCE A FAIR BIT OF
14 SCIENCE DOWN MY THROAT, BUT IT WAS AGAINST MY WILL. BUT THERE
15 IS ENGLISH IN THIS PATENT.

16 AND ONE THING THAT I THINK MERCK DID NOT DO IN THEIR
17 PRESENTATION IS WALK YOU THROUGH THE PERTINENT PORTIONS OF THE
18 PATENT THAT RELATE TO CLAIM CONSTRUCTION HERE.

19 SO I'M GOING TO DO THAT AS WELL, AND I THINK YOUR HONOR
20 IS GOING TO SEE QUITE A BIT OF IT IS IN ENGLISH AND IT DOES
21 CLEARLY STATE, AS MR. RABINOWITZ CLEARLY CONCEDED, THAT THERE
22 ARE PRODRUGS IN THIS CLAIM, BECAUSE THE POINT I WILL BE MAKING
23 IS THAT MY PRODRUG ISN'T ONE OF THEM.

24 THE COURT: WELL, BUT I DON'T THINK MR. RABINOWITZ
25 SAID THERE WERE NO PRODRUGS IN THE CLAIM, HE SAID THAT THEY

1 WERE EXAMPLES.

2 MR. MCCANN: THE CLAIM IS WHAT COVERS, IS WHAT
3 IDENTIFIES WHAT YOU OWN AS THE PATENT HOLDER. AND WE DO HERE
4 HAVE TO CONSTRUE THAT CLAIM AND DETERMINE WHAT ARE THE LIMITS,
5 WHAT ARE THE BOUNDARIES OF THAT CLAIM.

6 SO AS I'M GOING TO SHOW YOU YOUR HONOR, THE FACT THAT
7 THEY HAVE PRODRUGS IN THE CLAIM -- IN FACT, WHY DON'T I INSTEAD
8 OF TALKING IN ABSTRACTS, WHY DON'T WE GO TO IT.

9 AND THERE ARE TWO ISSUES THAT GILEAD THINKS, TWO SETS OF
10 LANGUAGE THAT GILEAD THINKS SHOULD BE INCLUDED IN THE
11 DEFINITION HERE.

12 THE FIRST, WITHOUT REFERENCE TO IN VIVO TRANSFORMATION.
13 AND THE SECOND, THAT THE PRODRUGS ARE LIMITED TO THOSE CLAIMED.

14 I'M GOING TO TAKE THEM ONE AT A TIME IN REVERSE ORDER, SO
15 I'M GOING TO BEGIN WITH, THE PRODRUGS ARE LIMITED TO THOSE THAT
16 ARE CLAIMED.

17 AND I'M NOW SHOWING YOUR HONOR ON SLIDE 3 FROM THE PATENT
18 AT COLUMN 32, LINES 5 TO 8, THIS DEFINITION WHICH IS THE HEART
19 OF OUR DISCUSSION TODAY. AND AS YOUR HONOR NOTED, WE ARE NOT
20 DISPUTING, WE ARE FINE WITH THE LANGUAGE AS FAR AS IT GOES,
21 ADMINISTERING SHOULD BE UNDERSTOOD TO MEAN PROVIDING A COMPOUND
22 OF THE INVENTION OR A PRODRUG OF THE COMPOUND OF THE INVENTION,
23 THAT'S FINE.

24 THE PROBLEM IS, WHAT PRODRUG? ANY PRODRUG? ANY
25 POSSIBILITY?

1 AND YOUR HONOR WAS FOCUSED ON THAT IN YOUR COMMENTS TO
2 MR. RABINOWITZ, FOR ONLY THOSE PRODRUGS EXPRESSLY CLAIMED.

3 AND THEN THE SECOND ISSUE IS GOING TO RELATE TO
4 COMPOUNDS, WHAT COMPOUNDS? THE COMPOUNDS THAT THE DOCTOR
5 PROVIDES OR THE COMPOUNDS THE BODY PROVIDES TOO?

6 YOUR HONOR, WHEN YOU WERE SPEAKING TO MR. RABINOWITZ YOU
7 WERE ASKING ABOUT THE DEFINITION, AND SHOULD THE COURT JUST
8 APPLY THE DEFINITION BECAUSE IT CERTAINLY IS SIMPLE AND, YOU
9 KNOW, I GUESS EASILY APPLIED, THERE IT IS.

10 AND I THINK THERE'S THIS QUESTION OF, DOES THE COURT HAVE
11 THE AUTHORITY TO CHANGE THE DEFINITION AT ALL OR TO FURTHER
12 EXPLAIN WHAT IT MEANS IS PROBABLY A BETTER WAY OF SAYING IT.

13 AND THE ANSWER TO THAT QUESTION IS YES. AS YOUR HONOR
14 KNOWS, IN THE MARKMAN PROCESS YOU DON'T JUST LOOK AT THE
15 LANGUAGE IN THE SPECIFICATION, YOU HAVE TO CONSIDER THE WHOLE
16 PATENT IN CONSTRUING THE TERM. YOU HAVE TO LOOK AT THE CLAIM,
17 YOU HAVE TO LOOK AT THE SPECIFICATION, YOU HAVE TO LOOK AT THE
18 FILE WRAPPER, AND ALTHOUGH IT'S LESS IMPORTANT, YOU ALSO HAVE
19 TO LOOK AT EXTRINSIC EVIDENCE.

20 WHEN YOU ARE DEALING WITH A SPECIFIC DEFINITION IN A
21 PATENT, YOU DON'T JUST HAVE TO ACCEPT IT AS WRITTEN. I THINK A
22 REALLY IMPORTANT CASE ON THIS IS ALLERGAN V. APOTEX CASE. I
23 LOVE IT FOR TWO REASONS, ONE IT HELPS ME MAKE MY POINT, AND THE
24 OTHER ONE IS IT'S MY CASE.

25 THE COURT: TWO GOOD REASONS.

1 MR. MCCANN: YES.

2 THIS CASE, IT DEALT WITH A PATENT, YOUR HONOR, ABOUT HAIR
3 GROWTH, SPECIFICALLY EYELASHES. AND THAT'S WHAT THE DRUG DID,
4 IT MADE YOUR EYE LASHES LONGER AND THICKER AND DARKER. AND
5 THERE WAS A DEFINITION IN THE SPECIFICATION, AND I HAVE IT HERE
6 ON THE SCREEN, AND IT SAID, OKAY, IN THIS CLAIM, TREATING HAIR
7 LOSS, THAT MEANS, ARRESTING HAIR LOSS, REVERSING HAIR LOSS OR
8 BOTH, AND PROMOTING HAIR GROWTH.

9 AND WHEN I FIRST READ THAT DEFINITION I THOUGHT THE SAME
10 THING THAT THE DEFENDANTS WERE THINKING WHICH IS, MY CLIENT
11 ALLERGAN HAS A BIG PROBLEM HERE BECAUSE THE DRUG FROM THEIR
12 PERSPECTIVE ONLY PROMOTED HAIR GROWTH.

13 AND WHEN YOU READ THAT DEFINITION IT SAYS, NO, IT MEANS
14 ARRESTING HAIR LOSS OR REVERSING HAIR LOSS. SO THAT'S SORT OF
15 A AND B, BUT YOU ALSO HAVE TO DO C, PROMOTING HAIR GROWTH. YOU
16 HAVE TO HAVE A AND B AND C.

17 AND THAT CASE WE ARGUED TO THE DISTRICT COURT AND IT WENT
18 TO THE FEDERAL CIRCUIT. AND THE FEDERAL CIRCUIT SAID, EVEN
19 THOUGH THAT WORD SAYS AND, TREATING HAIR LOSS MEANS ARRESTING
20 HAIR LOSS, REVERSING HAIR LOSS OR BOTH, AND PROMOTING HAIR
21 GROWTH, IT REALLY IS OR.

22 AND ONLY IN THE PATENT WORLD COULD AND MEAN OR. BUT THE
23 REASON THE FEDERAL CIRCUIT SAID IS WHEN YOU LOOK AT THE ENTIRE
24 PATENT, NOT JUST THE DEFINITION BUT THE WHOLE PATENT, YOU CAN
25 SEE THAT THERE ARE MANY EXAMPLES OF THE DRUG BEING USED WHERE

1 THE DISCLOSURE SAYS IT'S JUST PROMOTING HAIR GROWTH.

2 SO THE FEDERAL CIRCUIT SAID YOU HAVE TO READ THIS
3 DEFINITION IN CONTEXT OF THAT INFORMATION. AND WITH THAT IN
4 MIND, THIS CLAIM WILL COVER A DRUG THAT ONLY PROMOTES HAIR
5 GROWTH, DESPITE THAT "AND."

6 AND THAT IS THE SAME AS YOU HAVE HERE, YOUR HONOR. YOU
7 HAVE A DEFINITION, BUT THERE'S SOME CLARIFICATION REQUIRED.
8 AND THE CLARIFICATION REQUIRED HERE IS WHAT IS THE WORLD OF
9 PRODRUGS THAT WE ARE TALKING ABOUT. IS IT ALL OF THEM THAT CAN
10 BE USED TO TREAT HCV THAT METABOLIZES TO ONE OF THE STRUCTURES
11 IN THE CLAIM, OR IS IT JUST THE ONES THAT MERCK PUT INTO THE
12 CLAIM?

13 SO WHAT I DID, YOUR HONOR, TO TRY TO HELP MAKE MY POINT
14 IS I TOOK THE CLAIM, HERE CLAIM 1, THIS IS ON SLIDE 6 NOW, AND
15 I REPLACED THE WORD ADMINISTERING WITH THE DEFINITION THAT
16 MERCK IS PROPOSING. SO I'M GOING TO DO THAT IN THE NEXT SLIDE.

17 AND YOUR HONOR HAD ACTUALLY SAID IN YOUR COMMENTS
18 EARLIER, AREN'T YOU REALLY ASKING ME TO REPLACE THESE WORDS?
19 AND I FELT REALLY GOOD ABOUT MYSELF RIGHT THEN BECAUSE I
20 THOUGHT, WELL GOOD, I THOUGHT AHEAD ENOUGH THIS TIME.

21 THE COURT: BECAUSE THAT WOULD THEN GIVE ME THE EASY
22 ABILITY TO CONSTRUE THESE OTHER TERMS.

23 AND IN FACT MR. RABINOWITZ EFFECTIVELY WANTS ME TO DO
24 THAT AS WELL BY EXPRESSLY REJECTING YOURS, BUT YOU'RE ADDING
25 CONSTRUCTION BY SUPPORTING HIS.

1 MR. MCCANN: YES.

2 SO WHAT I'M GOING TO SHOW YOU, YOUR HONOR, THERE HAS BEEN
3 SOME DISCUSSION TOO ABOUT REDUNDANCY. AND I THINK THAT YOU
4 CAN, I THINK THAT THIS WILL MAKE CLEAR MY FUNDAMENTAL POINT,
5 THIS SLIDE AND THE NEXT ONE.

6 SO WHEN YOU REPLACE ADMINISTERING WITH MERCK'S PROPOSED
7 DEFINITION, NOW IT SAYS, A METHOD OF TREATING HCV COMPRISING
8 PROVIDING TO THE INDIVIDUAL IN NEED, AN EFFECTIVE AMOUNT OF A
9 COMPOUND OF THE INVENTION OR A PRODRUG OF A COMPOUND OF THE
10 INVENTION.

11 MR. RABINOWITZ AGREED, I THINK EVERYONE AGREES THAT
12 FIRST, THE COMPOUND OF THE INVENTION, THAT IS DEFINED BY WHAT
13 WE TOLD YOU IN THE TECH TUTORIAL IS CALLED THE MARKUSH GROUP,
14 AND THE SPECIFIC CHEMISTRY YOU CAN APPLY TO EACH OF THE
15 VARIABLES. NO ONE IS SAYING OTHERWISE, WE ALL AGREE.

16 SO IN OTHER WORDS, SALICYLIC ACID WHICH IS WHAT ASPIRIN
17 CONVERTS TO, THAT'S NOT HERE. SO NO ONE IS GOING TO SAY THAT A
18 COMPOUND OF THE INVENTION WOULD INCLUDE SALICYLIC ACID. BUT
19 WHAT ABOUT ASPIRIN? THAT'S NOT IN HERE EITHER. THE PRODRUG.

20 IN OTHER WORDS, COMPOUND OF THE INVENTION IS DESCRIBED BY
21 THE SCOPE OF THE CLAIM AND SO IS PRODRUG OF A COMPOUND OF THE
22 INVENTION.

23 I'M GOING TO SHOW YOU IN A MOMENT, YOUR HONOR SAID I
24 REALLY DON'T KNOW WHICH OF THESE THINGS ARE PRODRUGS AND WHICH
25 ARE NOT. I'M GOING TO FOCUS ON THE TWO THAT ARE HIGHLIGHTED.

1 ACYL DERIVATIVES IN YELLOW, THEN SOMETHING CALLED SATE IN BLUE,
2 BECAUSE THE PATENT IN THE SPECIFICATION TELLS YOU THAT THOSE
3 ARE PRODRUGS.

4 BUT I THINK AS YOUR HONOR OBSERVED, EVERYTHING IN THIS
5 CLAIM EXCEPT FOR THE -- THIS ONE, THE TRIPHOSPHATE, EVERYTHING
6 CONVERTS TO SOMETHING ELSE IN ORDER TO WORK.

7 SO WHEN YOU LOOK AT THE Y POSITION --

8 THE COURT: SO, OKAY. THIS IS --

9 MR. MCCANN: THE FUN PART.

10 THE COURT: WELL, I NEED YOU TO BACK UP BECAUSE MY, I
11 MEAN, I MIGHT FOLLOW YOU NOW, AND THE MINUTE I GET OUT THE
12 DOOR, I WON'T.

13 MR. MCCANN: UNDERSTOOD.

14 THE COURT: IT DOES NO GOOD FOR ME TO PRETEND LIKE
15 THIS IS MAKING SENSE. I NEED YOU TO KNOW HOW BASIC YOU HAVE TO
16 BE.

17 AND YOU HAVE TO TELL ME HOW MUCH OF THIS IS IMPORTANT FOR
18 ME TO BE ABLE TO CONSTRUE THESE TERMS.

19 MR. MCCANN: OKAY. I UNDERSTAND, YOUR HONOR.

20 SO WHAT I WANT TO DO IS FIRST FOCUS YOU ON Y. DO YOU
21 REMEMBER FROM THE TECH TUTORIAL, THAT'S THE PART OF THE DRUG
22 THAT CHANGES THROUGH METABOLISM.

23 SO YOU BEGIN WITH THAT PRODRUG MOIETY AND THAT COMES OFF,
24 AND EVENTUALLY THE FIRST PHOSPHATE AND THEN THE SECOND
25 PHOSPHATE AND THE THIRD PHOSPHATE ALL GET ADDED THERE AT Y.

1 AND THEN THAT IS WHAT THE ACTIVE DRUG THAT CAN LINK IN
2 AND BREAK THE CHAIN, BREAK THE ZIPPER LIKE WE TALKED ABOUT LAST
3 WEEK.

4 THE COURT: YES.

5 MR. MCCANN: LOOK AT Y IN THE CLAIM, AND I KNOW
6 YOUR HONOR IS NOT A CHEMIST AND NEITHER AM I, BUT A DEEP
7 KNOWLEDGE OF CHEMISTRY IS NOT REALLY REQUIRED TO UNDERSTAND
8 THIS.

9 SO Y CAN BE A SERIES OF THINGS, ONE OF THEM AS THE THREE
10 PHOSPHATES.

11 THE COURT: AND THAT'S THE P3 --

12 MR. MCCANN: P309H4.

13 THE OTHERS ARE ALL SOMETHING ELSE. SO THEY ARE ALL
14 THINGS THAT CHANGE IN THE BODY FROM HOW THEY STARTED TO BE P3.

15 THIS PATENT --

16 THE COURT: SO THOSE ARE OTHER PRODRUGS IN A SENSE.

17 MR. MCCANN: YOU COULD THINK OF IT THAT WAY.

18 ACTUALLY, YOUR HONOR, I HAVE TO TELL YOU, I THINK A
19 PRODRUG EXPERT WOULD TELL YOU THAT THE ONE I HAVE IN BLUE AND
20 THE ONE I HAVE IN YELLOW, THOSE ARE WHAT A SCIENTIST WHO IS AN
21 EXPERT IN PRODRUGS WOULD CALL A PRODRUG.

22 THE COURT: SO THE ACT OF TRANSFORMATION, IN YOUR
23 VIEW, DOESN'T CREATE ADDITIONAL PRODRUGS.

24 MR. MCCANN: NO. AND THIS IS A BIT OF AN ASIDE
25 BECAUSE I DON'T THINK IT MATTERS TO THE ARGUMENT, BUT IT'S -- A

1 PRODRUG IS A DESIGNED THING, IT'S COMPLICATED.

2 SO FOR EXAMPLE, TAKING SOFOSBUVIR, AS I WAS EXPLAINING
3 LAST WEEK, THE TRICK WAS TO MAKE A PRODRUG OF THAT FIRST P, THE
4 MONOPHOSPHATE, IF YOU COULD DO THAT, THEN IT SEEMED TO WORK.

5 IF YOU DID A PRODRUG OF SOME OTHER RESULT, TWO P'S OR OH
6 FOR EXAMPLE, IT WOULD BREAK DOWN FOR SOME REASON.

7 SO NOT ALL THESE THINGS I THINK AN EXPERT WOULD CONSIDER
8 TO BE A PRODRUG. IT DOESN'T MATTER, EITHER WAY THERE ARE
9 PRODRUGS THAT THIS PATENT CALLS PRODRUGS IN THIS CLAIM, AND
10 MR. RABINOWITZ AGREES THAT THEY ARE THERE.

11 SO THE ONES I'M GOING TO FOCUS ON ARE GOING TO BE ACYL
12 DERIVATIVES, THEN AT THE BOTTOM YOU SEE IN BLUE R9 AND R10, AND
13 THEN IT GIVES YOU THIS OCH₂ CH₂ SC (==O) T+BTYL. THAT'S
14 SOMETHING CALLED SATE, S-A-T-E, AND THAT IS A PRODRUG. AND
15 THAT IS ONE OF THE PRODRUGS THAT MERCK CLAIMS IN THIS PATENT
16 AND THE OTHER ACYL DERIVATIVES.

17 SO YOUR HONOR, IF YOU STEP BACK AND YOU THINK ABOUT THE
18 DEFINITION, IT SAYS A COMPOUND OF THE INVENTION OR A PRODRUG OF
19 THE COMPOUND OF THE INVENTION. THAT'S LIKE A CONCEPT, WHAT CAN
20 YOU GIVE THE PATIENT. I CAN GIVE A COMPOUND OR I CAN GIVE A
21 PRODRUG.

22 IN VERY SIMPLISTIC, AND I DON'T MEAN TO BE TOO
23 SIMPLISTIC, BUT IN VERY SIMPLE TERMS THAT'S LIKE SAYING YOU CAN
24 GIVE A FRUIT OR A VEGETABLE. BUT WHERE DO YOU FIND OUT WHICH
25 FRUIT AND WHERE DO YOU FIND OUT WHICH VEGETABLE? IT'S IN THE

1 CLAIMS AND IT'S IN THE WHOLE DISCLOSURE OF THE PATENT, AND IT'S
2 NOT EVERY FRUIT AND IT'S NOT EVERY VEGETABLE.

3 OKAY. I THINK YOUR HONOR FULLY UNDERSTANDS THIS POINT,
4 BUT JUST FOR CLARITY ON SLIDE 8, NO ONE DISPUTES THAT THE
5 PRODRUGS IN THIS CLAIM ARE NOT THE PHOSPHORAMIDATES OF
6 SOFOSBUVIR, IT'S NOT IN THERE. AND SO THE QUESTION IS CAN YOU
7 TAKE THAT WORD PRODRUG FROM THE SPECIFICATION AND EXPAND THE
8 UNIVERSE OF PRODRUGS BEYOND WHAT'S IN THE CLAIM TO GET ALL OF
9 THEM.

10 YOUR HONOR MENTIONED A NUMBER OF TIMES THAT THIS IS NOT
11 THE PROCEEDING FOR INVALIDITY, AND I'M NOT GOING TO TALK ABOUT
12 INVALIDITY, THAT WOULD BE A PROBLEM.

13 WE NEVER NEED TO GET THERE ON THIS PARTICULAR ISSUE
14 THOUGH BECAUSE WHEN YOU PROPERLY CONSTRUE THIS CLAIM, THERE'S
15 NO REASON IN THE RECORD FOR YOU TO GO BEYOND WHAT MERCK SAID
16 WAS THEIR INVENTION WHICH IS WHAT THEY DESCRIBED IN THE CLAIM,
17 AND IT'S NOT SOFOSBUVIR.

18 IF YOU ACCEPT MR. RABINOWITZ'S ARGUMENT THAT PRODRUG
19 EXPANDS AND COVERS ALL OF THEM, WHAT'S ACYL DERIVATIVE DOING IN
20 THE CLAIM? THIS IS NOW SLIDE 9. AND WHAT IS SATE DOING IN THE
21 CLAIM?

22 SO IF PRODRUGS COVERS ALL OF THEM, THOSE LIMITATIONS HAVE
23 NO MEANING. YOU WOULDN'T HAVE TO HAVE THAT THERE. WHAT YOU
24 WOULD HAVE IS MY COMPOUNDS OF THE INVENTION, FRANKLY THIS CLAIM
25 WOULD SAY P309H4 AND THEN THE REST OF THE CHEMISTRY THAT

1 DESCRIBES WHAT YOU DO NOT JUST AT Y BUT AT THE SUGAR RING AND
2 THE BASE.

3 YOU WOULDN'T NEED TO HAVE ANYTHING AT Y EXCEPT THE ACTIVE
4 METABOLITE. IF PRODRUG IS AS BROAD AS MR. RABINOWITZ SAYS, IT
5 IS A CANNON OF CLAIM CONSTRUCTION THAT YOU HAVE TO GIVE EFFECT
6 TO ALL LIMITATIONS OF THE CLAIM.

7 IF YOU INTERPRET PRODRUG TO HAVE NO BOUNDARY, THEN THAT
8 LANGUAGE, ACYL DERIVATIVES, MIGHT AS WELL BE STRUCK OUT AND
9 THAT LANGUAGE ABOUT SATE.

10 THE COURT: SO JUST TO BE CLEAR, IT'S UNDISPUTED THAT
11 SOFOSBUVIR IS NOT AN ACYL DERIVATIVE OR A SATE.

12 MR. MCCANN: IT IS NOT.

13 SO THAT'S THE CLAIM. AND AGAIN, THERE'S A HIERARCHY IN
14 ANALYZING CLAIM CONSTRUCTION, YOU DO BEGIN WITH THE CLAIM. AND
15 I THINK THE CLAIM ITSELF IS THE MOST POWERFUL EVIDENCE THAT
16 PRODRUG IS NOT UNBOUNDED HERE.

17 BUT LET'S GO THROUGH THE SPECIFICATION, AND THIS IS ALSO
18 THE POINT YOUR HONOR WHERE I WILL TIE THINGS UP AND SHOW YOU
19 FOR THE RECORD THAT ACYL DERIVATIVES AND SATE ARE PRODRUGS.

20 AGAIN, I DON'T THINK MERCK IS DISPUTING THIS.

21 OKAY. SO TO BEGIN WITH, HERE'S SATE. THIS IS EXAMPLE
22 72, IT'S AT, IT'S SLIDE 11, AND IT'S COLUMN 77 OF THE PATENT,
23 LINE 57 TO 67. AND SATE IS EXPRESSLY DESCRIBED HERE.

24 MR. RABINOWITZ WHEN HE WAS SPEAKING, HE SAID, YOU KNOW,
25 ONE OF THE THINGS THAT GILEAD IS TRYING TO DO IS IMPORT A

1 LIMITATION FROM THE SPECIFICATION INTO THE CLAIM, AND THAT'S
2 TOTALLY IMPROPER. AND HE'S ABSOLUTELY RIGHT THAT THAT IS
3 IMPROPER, YOU ARE NOT SUPPOSED TO DO THAT IN CLAIM
4 CONSTRUCTION.

5 I AM NOT IMPORTING SATE FROM EXAMPLE 72 INTO THE CLAIM.
6 IT'S IN THE CLAIM.

7 THE COURT: I'M LOOKING AT THE CLAIM. WHEN YOU SAY
8 IT'S IN THE CLAIM, LET'S BE CONCRETE.

9 MR. MCCANN: I WILL GO TO THE NON CROSSED OUT VERSION
10 IT'S OCH₂CH₂SC (==O)T+BUTYL.

11 THE COURT: I DON'T KNOW, I'M SORRY, I DO NOT KNOW
12 WHERE YOU ARE.

13 MR. MCCANN: THIS IS SLIDE 9 LOOKING AT CLAIM 1 OF
14 THE PATENT. AND THE VARIABLE R₉ AND R₁₀ BEING DEFINED AS THE
15 COMPOUND OR THE STRUCTURE OCH₂ CH₂ SC, THAT IS SATE.

16 THE COURT: ALL RIGHT. THAT'S LINE 14 AND 15 OF
17 COLUMN 138?

18 MR. MCCANN: YES.

19 THE COURT: THAT'S SATE. OKAY.

20 MR. MCCANN: ALSO JUST BRIEFLY, SATE, IS A MORE CLEAR
21 EXAMPLE OF A PRODRUG IN THE CLAIM.

22 AGAIN, MR. RABINOWITZ AGREES THEY ARE THERE BUT I JUST
23 WANT TO TOUCH ON ACYL DERIVATIVES. THIS IS IN THE PATENT,
24 COLUMN 38, LINES 11 TO 19.

25 THE COURT: COLUMN 138?

1 MR. MCCANN: COLUMN 38.

2 THE COURT: OH, 38.

3 MR. MCCANN: AND I DID FOR THE COURT'S BENEFIT, EVERY
4 PLACE I CITE THE PATENT IN THE PRESENTATION I PUT THE PINPOINT
5 CITATION. SO I KNOW THE COURT IS LOOKING NOW, BUT IT'S ALSO
6 GOING TO BE THERE FOR YOUR REFERENCE LATER.

7 SO AT COLUMN 38, LINES 11 TO 19, THE PATENT DESCRIBES THE
8 OTHER KIND OF PRODRUG, SPECIFICALLY IT SAYS, ALSO IN THE CASE
9 OF CARBOXYLIC ACID OR ALCOHOL GROUP BEING PRESENT IN THE
10 COMPOUNDS OF THE PRESENT INVENTION, PHARMACEUTICALLY ACCEPTABLE
11 ESTERS OF CARBOXYLIC ACID DERIVATIVES, SUCH AS METHYL, ETHYL,
12 OR PIVALOYLOXYMETHYL, OR ACYL DERIVATIVES OF ALCOHOLS, CAN BE
13 EMPLOYED. INCLUDED WITHIN THE CONCEPT HERE ARE THOSE ACYL
14 GROUPS KNOWN IN THE ART FOR MODIFYING THE SOLUBILITY OR
15 HYDROLYSIS CHARACTERISTICS FOR USE AS SUSTAINED-RELEASE OR
16 PRODRUG FORMULATIONS.

17 AND THAT'S NOT QUITE IN ENGLISH IT'S NOT AS CLEAR AS
18 SATE. BUT WHAT THAT SAYS IS ACYL DERIVATIVES CAN BE USED TO
19 MAKE PRODRUGS AND THAT'S ONE OF THE CLASSES THAT MERCK CHOSE TO
20 PUT IT TO THE CLAIM.

21 NOW I WANT TO GO BACK

22 THE COURT: SO I'M, WHEN I LOOK AT THE CLAIM ITSELF,
23 SO IT IS ADMINISTERING A COMPOUND BY STRUCTURAL FORMULA III OR
24 A PHARMACEUTICALLY ACCEPTABLE SALT OR ACYL DERIVATIVE THEREOF.
25 SO THE SALT IS THE SATE.

1 MR. MCCANN: NO, SATE IS JUST THIS ONE IN BLUE AT THE
2 BOTTOM RIGHT. WELL, IT'S THE R9, R10, AS I DESCRIBED BEFORE.

3 THE COURT: NO, I KNOW THAT. SO I HAVE TO -- BECAUSE
4 I'M TRYING TO UNDERSTAND THE CLAIM AND I APOLOGIZE.

5 MR. MCCANN: IT'S ALL RIGHT, YOUR HONOR.

6 THE COURT: I'VE GOT ACYL DERIVATIVE WRITTEN HERE. I
7 SEE THAT THE R9 AND R10 ARE, AND THEN IT GOES ON. BUT ACYL --

8 MR. MCCANN: LET ME JUST EXPLAIN IT THIS WAY,
9 YOUR HONOR, THE ACYL DERIVATIVE, THAT'S MULTIPLE THINGS THAT
10 CAN SERVE AS A PRODRUG. THE SATE THAT'S CLAIMED HERE, IT'S
11 JUST ONE KIND OF SATE.

12 SO SATE ITSELF, IF YOU LOOK IN THE PATENT, THERE ARE A
13 COUPLE OF DIFFERENT VARIANTS, BUT THEY CHOSE ONLY TO CLAIM ONE
14 OF THEM AND IT'S THE SPECIFIC CHEMICAL STRUCTURE THAT YOU SEE
15 THERE.

16 AND SO WHAT THAT MEANS IS THE PERSON DRAFTING THIS CLAIM
17 DIDN'T WANT TO BE LIMITED TO A PARTICULAR ACYL DERIVATIVE SO
18 THEY JUST CALLED IT ACYL DERIVATIVES.

19 THE COURT: CLAIMING THE ENTIRE CATEGORY.

20 MR. MCCANN: YES, WHATEVER THAT ENTAILS.

21 BUT WHEN IT CAME TO SATE, FOR THEIR OWN REASON THEY CHOSE
22 TO LIST JUST SPECIFICALLY THE EXACT CHEMICAL FORMULA YOU SEE
23 THERE.

24 AND SO IF SOMEONE IS MAKING A DIFFERENT KIND OF SATE AS A
25 PRODRUG, IT WOULDN'T BE COVERED BY THIS CLAIM. JUST THE ONE

1 THAT MERCK CHOSE TO CLAIM.

2 I THOUGHT, YOUR HONOR, SOME OF THIS IS, YOU ASKED ME LAST
3 WEEK TON CONCRETE AND I WAS TRYING TO THINK OF WHAT IS A GOOD
4 WAY TO SHOW YOU THAT MERCK DID NOT CHOOSE TO GRAB OR TO CLAIM
5 THE WHOLE UNIVERSE OF PRODRUGS THAT MIGHT APPLY IN THIS FIELD
6 BUT JUST THESE SPECIFIC ONES. AND THE ANSWER TO THAT IS IN THE
7 PATENT ITSELF. THE ANSWER TO THAT QUESTION AND THE CONCRETE
8 EXAMPLE.

9 IN MERCK'S PATENT AT THE SAME PLACE, EXAMPLE 72, WE ARE
10 LOOKING AT SLIDE 13, THERE'S A REFERENCE TO THIS PAPER BY
11 SOMEONE NAMED WAGNER. AND MERCK ACTUALLY DISCUSSED THE WAGNER
12 REFERENCE IN ITS REPLY BRIEF. AND I THINK WAGNER IS VERY
13 INFORMATIVE OF THIS QUESTION OF, DID MERCK SORT OF COVER ALL
14 THE BASES ON PRODRUGS HERE.

15 SO WAGNER IS WRITTEN IN 2000 AS IT TELLS YOU HERE AT
16 COLUMN 77 BEGINNING AT LINE 57, PUBLISHED IN 2000, AND
17 YOUR HONOR WILL RECALL THAT MERCK'S PRIORITY DATE FOR THIS
18 PATENT IS FEBRUARY 2002.

19 THE COURT: YEAH.

20 MR. MCCANN: SO THIS IS IN THE TIME FRAME THAT THE
21 WORK IS BEING DONE. AND THE MERCK INVENTORS ARE AWARE OF WHAT
22 WAGNER SAYS AND THEY INCORPORATE WHAT HE SAYS BY REFERENCE.
23 I'M SAYING HE, IT MIGHT BE A SHE, WAGNER I WILL SAY.

24 SO WAGNER WHICH IS ATTACHED TO MERCK'S REPLY BRIEF, IT'S
25 DOCKET NUMBER 99-2, EXHIBIT A TO THE REPLY BRIEF. IT'S A GOOD

1 20 PAGES OF REALLY SMALL FONT TALKING ALL ABOUT PRODRUGS IN
2 THIS FIELD USING NUCLEOSIDES TO TREAT DISEASES LIKE HCV.

3 AND WHAT I DID HERE, YOUR HONOR, IS I TOOK THE PARAGRAPH
4 HEADINGS THROUGHOUT WAGNER AND POINTED OUT ALL THE DIFFERENT
5 PRODRUG APPROACHES THAT WAGNER IDENTIFIED AS POSSIBILITIES IN
6 2000. AND I BLOCKED IN RED ALL OF THE DIFFERENT KINDS THAT ARE
7 NOT EXPRESSLY SET FORTH IN THE CLAIM, AND I PUT IN BLUE SATE
8 WHICH IS THE ONE THAT MERCK CHOSE TO PUT IN ITS CLAIM.

9 A COUPLE OF POINTS TO MAKE WITH IS THIS, YOUR HONOR. THE
10 FIRST IS, AND WE HAVE THE CASE CITATIONS IN OUR BRIEF, IF
11 YOU'RE AWARE OF SOMETHING AND YOU -- OF AN IDEA AND OF A
12 CONCEPT AND YOU DISCLOSE THAT IN YOUR PATENT AND YOU CHOOSE NOT
13 TO CLAIM IT THEN THAT INFORMED OR THAT IDEA IS DEDICATED TO THE
14 PUBLIC.

15 AND THAT'S WHAT MERCK DID HERE, THEY CLAIMED SATE BUT NOT
16 ALL OF THESE OTHER POSSIBILITIES. SO THAT'S POINT NUMBER ONE.

17 THE SECOND POINT IS, AND THIS REALLY GETS AT FAIRNESS,
18 WAGNER ON THE VERY LAST PAGE, PAGE 443, AGAIN THAT'S DOCKET
19 99-2, ON THE VERY LAST PAGE HE GOES THROUGH ALL THESE
20 POSSIBILITIES OF PRODRUGS, BUT THEN HE SORT OF FINISHES BY
21 EXPLAINING WHAT IS THE STATE OF THIS ART AT THAT TIME IN 2000.

22 AGAIN, AROUND THE SAME TIME MERCK IS DOING ITS WORK.

23 AND HE SAYS, UNFORTUNATELY THE EFFECTS OF A PRO
24 NUCLEOTIDE DESIGN, THAT'S WHAT WE ARE TALKING ABOUT HERE ARE
25 PRODRUGS OF THESE NUCLEOSIDES, ON THE MECHANISM OF NUCLEOTIDE

1 RELEASE HAVE ONLY BEEN SYSTEMICALLY STUDIED IN A FEW CASES.
2 THE IN VIVO POTENCY, HOW EFFECTIVE THE DRUG IS, THE LONG-TERM
3 TOXICITY, YOU ARE TRYING TO CURE THE CELL, NOT KILL IT, THE
4 BIOAVAILABILITY, CAN YOU GET YOUR DRUG WHERE IT NEEDS TO BE,
5 PLASMA PHARMACOKINETICS, AND TISSUE DISTRIBUTION HAVE BEEN
6 DETERMINED FOR ONLY A FEW PRO NUCLEOTIDES. UNLIKE THE IN VITRO
7 EXPERIMENTS CONDUCTED WITH KINASE DEFICIENT CELLS, DIRECT PROOF
8 OF IN VIVO DELIVERY OF NUCLEOTIDES REMAINS ELUSIVE AND WILL
9 UNDOUBTEDLY RELY ON A PARTICULAR TECHNIQUE FOR FINDING OUT
10 WHETHER YOUR DRUG GOT TO THE RIGHT PLACE.

11 AND THAT'S ALMOST ENGLISH, YOUR HONOR, BUT WHAT IT'S
12 SAYING IS THIS IS HARD, THIS IS DIFFICULT, AND NOT ALL OF THESE
13 THINGS ARE GOING TO WORK.

14 AND I BEGAN MY PRESENTATION BY SAYING OF THE 154 IDEAS IN
15 THIS PATENT, NONE OF THEM SUCCEEDED IN GETTING TO CLINIC.

16 IT IS UNFAIR TO CLAIM SATE AND ACYL DERIVATIVE AS YOUR
17 PRODRUGS AND THEN TO COME BACK 13 YEARS LATER WHEN SOMEONE ELSE
18 USES A DIFFERENT TECHNIQUE, ONE THAT'S NOT EVEN IN WAGNER, NOT
19 EXACTLY WAGNER, USES A DIFFERENT TECHNIQUE TO COME UP WITH A
20 WAY OF GETTING A DRUG THAT DOES HAVE POTENCY, THAT DOES NOT
21 HAVE TOXICITY, THAT IS BIOAVAILABLE, THAT HAS THE RIGHT TISSUE
22 DISTRIBUTION, AND THEN SAY BECAUSE I HAVE THAT WORD PRODRUG
23 FLOATING AROUND IN MY SPECIFICATION, I HAVE THAT BASE COVERED
24 AND YOU OWE ME MONEY. THAT IS NOT FAIR.

25 AND IT IS ALSO NOT SUPPORTED IN THE CLAIM CONSTRUCTION OF

1 THIS CLAIM TERM.

2 THE COURT: WELL, I STARTED OUT BY HAVING THAT
3 CONCERN THAT THE TERM PRODRUG IS SUCH A GENERIC GENERAL TERM
4 THAT IT TROUBLED ME THAT ALL UNKNOWN, UNDISCOVERED, UNAPPLIED
5 PRODRUGS COULD BE UNDER THE UMBRELLA OF THIS PATENT.

6 BUT THEN I REALIZED THAT MAY BE AN INVALIDITY ISSUE HERE
7 THAT I'M NOT GOING TO ADDRESS. SO I NEED TO BE CAREFUL TO TAKE
8 THIS ONE STEP AT A TIME AND PROPERLY CONSTRUE THE TERM AND THEN
9 LET THE CHIPS FALL WHERE THEY MAY WITH THE JURY ON THE ISSUE OF
10 INVALIDITY, BECAUSE I'M AFRAID THAT IN FACT YOU'RE INVITING THE
11 INVALIDITY ARGUMENT TO BE DRESSED UP AS A CLAIMS CONSTRUCTION.

12 MR. MCCANN: I GUESS, YOUR HONOR, THAT WOULD BE TRUE
13 IF SATE WASN'T IN THE CLAIM.

14 SO THERE IS INVALIDITY PROBLEM IF PRODRUG IS THAT BROAD
15 AND WE ARE NOT HERE TODAY FOR THAT. BUT IT NEVER HAS TO GET TO
16 THERE BECAUSE --

17 THE COURT: SO WHERE DOES IT SAY IT'S ONLY SATE AND
18 ACYL DERIVATIVE? I KNOW, I SEE IN THE CLAIM ITSELF YOU ARE
19 TELLING ME THAT SATE AND ACYL DERIVATIVES ARE CALLED OUT.

20 MR. MCCANN: BUT THE CLAIM IS NOT AN EXAMPLE,
21 YOUR HONOR.

22 SO IN A PATENT YOU HAVE REALLY TWO BIG PARTS, CLAIM, THAT
23 IS WHAT YOU INVENTED, THAT IS WHERE YOU SAY THIS IS THE
24 PROPERTY THAT I OWN. SOMETIMES, MANY TIMES, YOU DO NEED TO
25 LOOK AT THE SPECIFICATION TO UNDERSTAND WHERE DOES IT BEGIN AND

1 WHERE DOES IT END.

2 EVERY TIME YOU SHOULD LOOK AT THE SPECIFICATION FOR THAT
3 PURPOSE.

4 MY POINT TO YOU IS THIS, THE FACT THAT SATE AND ACYL
5 DERIVATIVES ARE IN THE CLAIM, THOSE AREN'T EXAMPLES, THAT'S
6 WHAT THEY ARE SAYING THAT THEY INVENTED HERE.

7 MAYBE IF I SAY IT THIS WAY, I CAN MAKE MYSELF MORE CLEAR.

8 LET'S SAY THAT SATE WAS NOT THERE AND ACYL DERIVATIVES
9 WAS NOT THERE AND IT JUST SAID, ADMINISTER A COMPOUND OF THE
10 INVENTION OR A PRODRUG OF THE COMPOUND OF THE INVENTION. AND
11 SATE WAS EXAMPLE 72 IN THE SPECIFICATION, AND I WAS STANDING
12 HERE ARGUING TO YOU, JUDGE, YOU'VE GOT TO LIMIT PRODRUGS TO
13 SATE AND ACYL DERIVATIVES BECAUSE THAT'S WHAT THEY DISCLOSED
14 HERE.

15 MR. RABINOWITZ WOULD STAND UP AND HE WOULD BE POUNDING ME
16 SAYING, YOU ARE TRYING TO IMPORT A LIMITATION FROM THE
17 SPECIFICATION INTO THE CLAIM AND THAT'S IMPROPER.

18 THE COURT: THAT'S WHAT HE SAID.

19 MR. MCCANN: THAT'S WHAT HE SAID. THAT IS WHEN THE
20 LIMITATION IS NOT THERE AND YOU ARE TRYING TO IMPORT IT.

21 IN THIS CLAIM OF THIS PATENT, THE LIMITATION IS IN IT. I
22 DIDN'T PUT IT THERE. STEPHEN S. CARROLL PUT IT THERE AND HIS
23 FELLOW INVENTORS, THEY CHOSE TO LIMIT THEIR PRODRUGS TO THE
24 ONES THAT THEY CLAIMED.

25 AND AGAIN, IT IS UNFAIR, AND I DON'T MEAN THAT JUST IN

1 THE VALIDITY CONTEXT, IT'S IMPROPER TO EXPAND PRODRUG BEYOND
2 WHAT THESE INVENTORS ACTUALLY INVENTED.

3 THE COURT: IN ORDER FOR ME TO PROVIDE THE RULING
4 THAT WOULD INCORPORATE MORE LIMITATIONS, I WOULD NEED TO ALSO
5 DEFINE THESE DERIVATIVE TERMS.

6 MR. MCCANN: IT'S A GOOD QUESTION, YOUR HONOR. WHEN
7 WE DRAFTED THIS BRIEF AND MADE OUR PROPOSAL, WHAT WE PROPOSED
8 WAS THAT THE CONSTRUCTION JUST GIVE THAT DEFINITION FROM THE
9 SPECIFICATION AND THEN SAY, EXCEPT THOSE PRODRUGS EXPRESSLY
10 CLAIMED.

11 AND WE FELT THAT WAS NOT -- THAT WAS ENOUGH GUIDANCE
12 BECAUSE THEN WE COULD ARGUE TO THE JURY AND MR. RABINOWITZ
13 COULD ARGUE TO THE JURY, THIS PHOSPHORAMIDATES IN THAT CLAIM
14 ARE NOT, THEY ARE NOT.

15 SO I THINK THAT WOULD BE CLEAR ENOUGH.

16 YOU COULD, I GUESS, TAKE OUR DEFINITION AND SAY, THE
17 PRODRUGS EXPRESSLY CLAIMED WHICH ARE ACYL DERIVATIVES, AND THEN
18 THAT CHEMICAL FORMULA. YOU KNOW, I DON'T KNOW THAT THAT'S
19 ACTUALLY NECESSARY FOR THE CLAIM CONSTRUCTION ORDER OR WHETHER
20 IF THIS CASE GETS TO A JURY THAT COULD BE HANDLED IN THE JURY
21 INSTRUCTION.

22 THE COURT: SO ARE YOU SUGGESTING -- WELL, THEN HELP
23 ME OUT BECAUSE YOUR CONSTRUCTION -- IS THE PROPER WAY OF
24 HANDLING THIS TO ACCEPT THE DEFINITION THAT THE PATENTEE
25 INCLUDED IN THE PATENT AND LEAVE THIS OTHER ISSUE TO THE JURY?

1 MR. MCCANN: I DON'T THINK SO BECAUSE I THINK THAT
2 THERE WILL BE A LOT OF FIGHTING AT THE TIME OF THE TRIAL AS TO
3 WHETHER THE PRODRUGS ARE LIMITED TO THOSE EXPRESSLY CLAIMED OR
4 ARE BROADER THAN THAT.

5 THE COURT: I GUESS -- THANK YOU.

6 AND I'M STILL LOOKING FOR THE MECHANISM THAT ALLOWS ME TO
7 EITHER ACCEPT YOUR DEFINITION OR TO EXPRESSLY REJECT IT WHICH
8 MR. RABINOWITZ WANTS. YOU BOTH WANT ME TO RESOLVE THIS ISSUE
9 NOW, THAT'S FINE, I'M STILL LOOKING FOR THE MECHANISM UNDER THE
10 LAW THAT ALLOWS ME TO DO IT.

11 AND YOU BRIEFED THAT I COULD GO OUT AND LOOK AT THE
12 DERIVATIVE CLAIMS, YOU GAVE ME A CASE THAT, THE ADVANCED FIBER
13 TECHNOLOGIES CASE, I BELIEVE.

14 MR. MCCANN: I THINK THE CASE YOUR HONOR IS LOOKING
15 FOR SPECIFICALLY WOULD BE ALLERGAN V. APOTEX, AND TRADING
16 TECHNOLOGIES. AND THE MECHANISM IS YOU CAN, AS THE JUDGE
17 CONSTRUING THE CLAIM, ELABORATE ON THE TERSE WORDS OF THE CLAIM
18 TO MAKE THEM MORE CLEARLY UNDERSTOOD.

19 ACTUALLY ALLERGAN AND TRADING TECHNOLOGIES, AND I SPOKE
20 ABOUT ALLERGAN BEFORE VERY BRIEFLY, IT SEEMED LIKE IT MEANT TWO
21 THINGS AND THE FEDERAL CIRCUIT SAID WHEN YOU REALLY UNDERSTAND
22 THIS PATENT IT'S ONLY ONE.

23 TRADING TECHNOLOGIES WAS SIMILAR, THERE WAS A DEFINITION,
24 I THINK IT WAS STATIC PRICE IN THE SPECIFICATION OF THAT
25 PATENT. AND THE ARGUMENT CONCERNED WHETHER THE COURT SHOULD

1 ADD A COUPLE OF WORDS TO THE DEFINITION OF STATIC PRICE TO MAKE
2 IT, MAKE THE DEFINITION FIT WITH WHAT WAS REALLY CLAIMED AND
3 INVENTED THERE.

4 AND THE COURT OF APPEALS SAID YES THAT'S FINE, YOU CAN
5 LOOK BEYOND THE TERSE WORDS IN THE SPECIFICATION AND LOOK AT
6 THE SCOPE OF THE CLAIM AND THE SPECK AND SEE WHAT DID THEY
7 REALLY INVENT HERE AND ELABORATE.

8 THE COURT: ALL RIGHT. OKAY.

9 I MEAN, YOU'RE THE ONE WHO GAVE ME THIS ADVANCED FIBERS
10 TECHNOLOGY CASE THAT SAYS HOWEVER IN THOSE CASES IN WHICH THE
11 CORRECT CONSTRUCTION OF A CLAIM TERM NECESSITATES A DERIVATIVE
12 CONSTRUCTION OF A NONCLAIM TERM --

13 MR. MCCANN: OH, I UNDERSTAND.

14 THE COURT: -- THE COURT MAY PERFORM THE DERIVATIVE
15 CONSTRUCTION IN ORDER TO ELUCIDATE THE CLAIMS MEANING.

16 MR. MCCANN: I'M SORRY, YOUR HONOR, I WAS ONE OFF ON
17 WHAT YOU ARE ASKING ABOUT.

18 YES. YOU CAN -- THAT CASE SAYS AND YOU CAN CONSTRUE A
19 WORD THAT IS ACTUALLY NOT IN THE CLAIM, BUT IT'S PART OF THE
20 CONSTRUCTION.

21 SO YOU HAVE --

22 THE COURT: THAT'S WHAT IT SEEMS LIKE YOU ARE BOTH
23 ASKING ME TO DO.

24 MR. MCCANN: YES.

25 AND SO WHAT I'M SAYING IS, I AM PROPOSING THAT THE PART

1 OF THE DEFINITION OF ADMINISTERING THAT INCLUDES PRODRUG OF THE
2 COMPOUND OF THE INVENTION, BE FURTHER CLARIFIED TO SAY, AND BY
3 THAT WE MEAN THE PRODRUGS THAT THE INVENTORS CLAIMED, NOT ALL
4 OF THEM.

5 THE COURT: ALL RIGHT. OKAY.

6 WELL, I THINK I UNDERSTAND THE MECHANISM AND -- I'M GOING
7 TO BE DOING THIS NO MATTER WHAT FOR EACH OF YOU IN ORDER TO
8 UNDER MR. RABINOWITZ'S ARGUMENT TO REJECT YOUR DEFINITION, I'M
9 GOING TO BE DOING THE SAME THING JUST WITH A DIFFERENT OUTCOME.

10 MR. MCCANN: UNDERSTOOD, YOUR HONOR.

11 THE COURT: OKAY.

12 MR. MCCANN: JUST BRIEFLY ON THE FILE HISTORY,
13 MR. RABINOWITZ I THINK HE DID ACCURATELY CHARACTERIZE WHAT
14 HAPPENED.

15 THE EXAMINER MADE A CHANGE AND THERE WAS NOT A LOT OF
16 DISCUSSION IN THE RECORD, AND WHAT I TAKE AWAY FROM IT IS THAT
17 THE LANGUAGE, AND I'M LOOKING HERE AT SLIDE 16, IT'S AN EXCERPT
18 FROM THE FILE HISTORY OF MERCK 5809.

19 IT ORIGINALLY SAID ESTER PRODRUG, AND IT WAS REPLACED
20 WITH THAT WORD ACYL DERIVATIVES.

21 AND MR. RABINOWITZ SAYS WELL, ESTER PRODRUG IS
22 DUPLICATIVE OF PRODRUGS HIGHER UP IN THE CLAIM SO THAT'S WHY IT
23 WAS TAKEN OUT.

24 AND YOU WOULD BE SURPRISED TO LEARN, YOUR HONOR, I SEE IT
25 DIFFERENTLY, AND I SEE --

1 THE COURT: BOTH OF YOU ARE SPECULATING THOUGH AT
2 THIS POINT.

3 MR. MCCANN: YES.

4 AND SO I ACTUALLY, YOU KNOW, IS THIS A CLEAR NON
5 MISTAKABLE DISAVOWAL -- I WILL ACTUALLY TAKE THAT BACK AND WHAT
6 I WILL SAY IS THEIR BEHAVIOR HERE IS ENTIRELY CONSISTENT WITH
7 WHAT I'M SAYING WHICH IS, IF THE ISSUE IS PRODRUG IS UP HERE
8 AND THAT'S ALL WE NEED, YOU COULD TAKE OUT ESTER PRODRUG, YOU
9 COULD NOT PUT IN ACYL DERIVATIVES AND YOU COULD KNOCK SATE OUT
10 OF THE Y GROUP IF YOU WERE TRYING, IF WHAT YOU WERE TRYING TO
11 DO IS MAKE CLEAR THAT YOU INTEND TO CLAIM ALL PRODRUGS. AND
12 THAT'S NOT WHAT THEY DID.

13 THE COURT: YEAH. OKAY.

14 MR. MCCANN: I HAVE BEEN GOING ON SOME TIME
15 YOUR HONOR, SO WHAT I'M GOING TO DO IS I'M GOING TO MOVE TO THE
16 SECOND ISSUE.

17 THE COURT: OKAY.

18 MR. MCCANN: THIS IS NOW SLIDE 22.

19 THE COURT: THANK YOU.

20 MR. MCCANN: SO THIS RELATES TO WHETHER ADMINISTERING
21 STOPS AT THE ACT OF GIVING BY THE DOCTOR OR SHOULD WE CONSTRUE
22 IT TO GO FURTHER TO SAY IT INCLUDES IN VIVO TRANSFORMATIONS.

23 AND FIRST, I AM NOT SAYING THAT PRODRUGS DON'T
24 METABOLIZE, OF COURSE THEY DO.

25 THE COURT: THEY DO. THAT'S THE WHOLE POINT.

1 MR. MCCANN: IF THEY WERE THE QUESTION, IF THAT WERE
2 THE ONLY FACT ONE WOULD NEED TO KNOW, THEN NO COURT WOULD EVER
3 DECIDE IN THE CASE OF A CLAIM THAT COVERS ONLY WHAT YOU PUT IN
4 THE PERSON'S MOUTH, THEY WOULD NEVER DECIDE THAT IT DOESN'T
5 REACH TO WHAT HAPPENS IN THE PERSON'S BODY, BUT COURTS DO.

6 AND WE CITED TO IN OUR PAPERS HOFFAMN LA-ROCHE AND
7 SCHERING V. GLENMARK. IN THOSE CASES COURT SAYS NO, IT DOESN'T
8 COVER WHAT HAPPENS IN THE BODY.

9 THE COURT: BUT THERE'S NO DEFINITION IN THOSE, WE
10 ARE LOOKING OUTSIDE TO THE GENERALLY UNDERSTOOD MEANING OF THE
11 TERM ADMINISTERING.

12 MR. MCCANN: I AGREE THAT THERE'S NO DEFINITION IN
13 THOSE.

14 BUT WHAT THE COURTS DID THERE, AND I THINK WHAT THIS
15 COURT STILL HAS TO DO, IS YOU HAVE TO GO THROUGH THE MARKMAN
16 PROCESS OF LOOK AT THE CLAIM, LOOK AT THE SPECIFICATION AND
17 DETERMINE WHETHER THE INVENTOR HERE, WITH THIS DEFINITION EVEN,
18 INTENDED TO REACH WHAT HAPPENS IN THE BODY.

19 AND I'M GOING TO START WITH MY BEST PIECE OF EVIDENCE AND
20 THEN I'M GOING TO I'M ACTUALLY NOT GOING TO START MY SLIDES
21 THAT WAY BUT I'M GOING TO START WITH THIS, TO SORT OF SET THIS
22 UP WITH YOU THEN I'M GOING TO WALK RELATIVELY QUICKLY THROUGH
23 THE POINTS.

24 MY BEST PIECE OF EVIDENCE ON THIS ISSUE IS YOUR HONOR
25 KNOWS THAT THE CRITICAL THING IN YOUR BODY IS THE FIVE PRIME

1 TRIPHOSPHATE, THE THREE P'S, AND A PRODRUG HAS TO BECOME THAT.

2 THIS PATENT TEACHES A WHOLE BUNCH OF DIFFERENT MOLECULES,
3 ONE OF THEM IS FIVE PRIME TRIPHOSPHATES. THAT'S THE P3 WE SAW
4 IN THE CLAIM. THIS PATENT TELLS YOU PUT THAT IN THE PILL TOO.

5 REMEMBER THIS IS IN 2002, AND IT MAY BE TODAY THAT PEOPLE
6 THINK THE ONLY WAY TO GO HERE IS A PRODRUG, BUT IN 2002 MAYBE
7 THEY FELT DIFFERENTLY.

8 ALL I KNOW IS AT EVERY POINT IN THE PATENT WHEN THEY TELL
9 YOU HOW TO ADMINISTER, THEY USE LANGUAGE, THEY USE TERMINOLOGY
10 THAT IS CONSISTENT WITH PUT THE DRUG IN THE PILL OR PUT THE
11 PRODRUG IN THE PILL BOTH AND GIVE IT TO A PATIENT.

12 THE COURT: BOTH OF THEM TOGETHER.

13 MR. MCCANN: WELL --

14 THE COURT: THE DRUG AND THE PRODRUG IS THAT WHAT YOU
15 SAID.

16 MR. MCCANN: WELL, IN OTHER WORDS, THIS PATENT
17 TEACHES YOU, YOU COULD PUT THE SATE PRODRUG IN A PILL, GIVE
18 THAT TO THE PATIENT OR YOU COULD PUT THE FIVE PRIME
19 TRIPHOSPHATE INTO A PILL.

20 SO WHAT I'M GETTING AT IS THIS, IF MR. RABINOWITZ IS
21 RIGHT, YOU WOULD HAVE EXPECTED THAT PATENT TO SAY, THIS FIVE
22 PRIME TRIPHOSPHATE, YOUR BODY MAKES THAT SO YOU SHOULD GIVE ONE
23 OF THESE COMPOUNDS OR PRODRUGS THAT'S GOING TO BECOME THAT BUT
24 IT SHOULDN'T SAY PUT THE FIVE PRIME TRIPHOSPHATE INTO A PILL.

25 EVERYTHING HERE SAYS THE ADMINISTER STOPS WITH THE

1 GIVING. AND I SEE YOUR HONOR IS A LITTLE PUZZLED.

2 THE COURT: WELL, I'M JUST TRYING TO LOOK BACK AT
3 THIS BECAUSE INTUITIVELY IT DOES, IT'S AN ACT OF DOING
4 SOMETHING AS OPPOSED TO THE ACT OF SETTING SOMETHING IN MOTION.

5 MR. MCCANN: YES.

6 THE COURT: SO, BUT I'M CAUTIOUS HERE BECAUSE OF THE
7 DEFINITION IN THE PATENT.

8 MR. MCCANN: I HAVE -- WHEN I WAS AN AUSA,
9 YOUR HONOR, MY DRUG CASES HAD MUCH BETTER PROPS THAN THEY DO
10 THESE DAYS, BUT I BROUGHT SOME DRUGS WITH ME. NONE OF THEM ARE
11 CONTROLLED SUBSTANCES.

12 THE COURT: GOOD TO KNOW.

13 MR. MCCANN: THIS MAY OR MAY NOT HELP YOU. I'M GOING
14 TO GO THROUGH AND EXPLAIN SOME OF THE CONCEPTS THAT I THINK ARE
15 IN THIS PATENT USING MY LITTLE PILLS HERE, AND I'M GOING TO DO
16 IT WITH SOME OF THE PRESENTATION.

17 SO I THINK WE ALL AGREE THAT -- I'M NOT SURE IF WE ALL
18 AGREE. I LOST THAT POINT, SO I'M GOING TO GO TO -- LET'S GO
19 ACTUALLY TO, I'M GOING TO START THIS WAY. I'M GOING TO START
20 WITH IN COMBINATION WITH, YOUR HONOR. THIS IS SLIDE 30.

21 I'M SORRY, I'M OUT OF ORDER, BUT I'M TRYING TO SORT OF
22 RESPOND TO WHAT I THINK ARE THE COURT'S CONCERNS IN THE ORDER
23 YOU ARE GIVING THEM TO ME. SO THIS IS SLIDE 30.

24 SO WE TOOK A LOOK AT CLAIM 2, AND IT'S APPROPRIATE WHEN
25 TRYING TO UNDERSTAND A CLAIM OF THE PATENT TO LOOK AT WHAT

1 OTHER CLAIMS SAY. AND IT SAYS, IN COMBINATION WITH.

2 AND MR. RABINOWITZ TOLD YOU BEFORE THAT WE ACTUALLY AGREE
3 ON THE DEFINITION OF WHAT THAT MEANS. AND IT'S IN THE
4 SPECIFICATION. WE TOOK IT RIGHT FROM THE SPECIFICATION. AND
5 IT MEANS, IN COMBINATION WITH, TOGETHER WITH, WHETHER GIVEN
6 SEPARATELY AT DIFFERENT TIMES DURING THE COURSE OF THERAPY OR
7 CONCURRENTLY IN DIVIDED OR SINGLE COMBINATION FORMS.

8 NOW HERE'S HOW I UNDERSTAND THAT, JUDGE, YOU CAN GIVE
9 SOFOSBUVIR, AND LET'S SAY RIBAVIRIN, TOGETHER IN ONE PILL AND
10 THAT'S MY DAYQUIL HERE, LARGE GEL-FILLED CAPSULE. OR YOU COULD
11 GIVE IT IN TWO PILLS. AND I COULD GIVE YOU, LET'S SAY
12 SOFOSBUVIR FIRST AND RIBAVIRIN LATER. SO THAT'S THE SEPARATELY
13 OR TOGETHER.

14 THE COURT: SURE.

15 MR. MCCANN: I DON'T SEE HOW THIS LANGUAGE COVERS
16 WHAT HAPPENS TO SOFOSBUVIR IN THE BODY.

17 AND WHAT I MEAN BY THAT IS THIS, SO I THINK I HAVE, I WAS
18 SHOWING YOU IN THE TECH TUTORIAL, THIS IS LOOKING AT SLIDE 40
19 FROM THE TECH TUTORIAL.

20 THE COURT: SORRY, 40?

21 MR. MCCANN: YES, YOUR HONOR.

22 THE COURT: YES, I HAVE SLIDE 40.

23 MR. MCCANN: SOFOSBUVIR, AS I WAS EXPLAINING IN THE
24 TECH TUTORIAL, IT GOES THROUGH ALL OF THESE TRANSFORMATIONS. I
25 GUESS I'M GOING TO COUNT, 1, 2, 3, 4, JUST TO GET IT TO THE

1 MONOPHOSPHATE. AND THEN AS YOU RECALL THAT HAS TO BECOME THE
2 DIPHOSPHATE, THAT BEING NUMBER FIVE, THEN THE TRIPHOSPHATE,
3 NUMBER SIX.

4 SO THIS THING CHANGES SIX TIMES FROM THE MOMENT YOU ARE
5 GIVEN THE DRUG TO WHEN IT'S ACTUALLY IN THE RIGHT PLACE IN YOUR
6 LIVER TO DO ITS JOB.

7 THIS LANGUAGE WITH IN CLAIM 2, THAT'S TALKING ABOUT DO I
8 GIVE THE DRUG TOGETHER IN ONE PILL OR ONE AT A TIME?

9 THE COURT: THAT'S WHAT YOU ARE SAYING THE CLAIM
10 SAYS?

11 MR. MCCANN: I'M SAYING THAT'S WHAT THE DEFINITION OF
12 IN COMBINATION WITH, WHAT CLAIM 2 IS REFERRING TO.

13 WHAT WE'VE SAID ON THE SLIDE HERE IT'S AN EX VIVO
14 CONCEPT, IT'S WHAT THE DOCTOR DOES.

15 THE COURT: OKAY. SO THE DEFINITION IS BROADER THAN
16 THE LANGUAGE HERE, I'VE GOT TO GO BACK TO.

17 MR. MCCANN: THE DEFINITION THAT THE PARTIES AGREED
18 ON, YOUR HONOR, IS ON SLIDE 31.

19 THE COURT: FOR "IN COMBINATION." I GUESS I'M A
20 LITTLE AT A LOSS.

21 MR. MCCANN: THE QUESTION IS WHEN DOES ADMINISTERING
22 STOP. WE DISCUSSED THE ORDINARY MEANING IS YOU GIVE IT AND YOU
23 ARE DONE.

24 THE COURT: SURE.

25 MR. MCCANN: AND THE QUESTION IS, DOES THIS PATENT

1 EVEN THOUGH IT SAYS PRODRUG, DOES THAT GO PAST YOU GIVE IT AND
2 IT'S DONE.

3 SO MY POINTS ARE GOING TO BE, I TOLD YOU MY BEST POINT,
4 I'M ACTUALLY GOING TO HIT THE BEST POINT AGAIN. BUT THE FIRST
5 ONE WAS THAT WHEN THIS PATENT TALKS ABOUT GIVING THE DRUG IN
6 COMBINATION WITH SOMETHING, IT'S REALLY REFERRING TO WHAT THE
7 DOCTOR IS DOING.

8 I DON'T THINK I'M MAKING A LOT OF PROGRESS WITH YOU ON
9 THAT ONE SO I'M GOING TO MOVE ON TO THE NEXT POINT, YOUR HONOR.
10 AND THAT IS, WHAT DOES THE PATENT SAY YOU DO WITH THE COMPOUNDS
11 OF THE INVENTION?

12 SO I'M LOOKING AT SLIDE 26. THIS IS CLAIM 1, THE TOP
13 PART OF IT. IT SAYS I HAVE A METHOD OF TREATING HEPATITIS C BY
14 ADMINISTERING AN AMOUNT OF A COMPOUND STRUCTURAL FORMULA III OR
15 A PHARMACEUTICALLY ACCEPTABLE SALT OR ACYL DERIVATIVE THEREOF.

16 MR. RABINOWITZ AND I BOTH AGREE PHARMACEUTICALLY
17 ACCEPTABLE SALT, ACYL DERIVATIVES, THESE ARE THING US MAKE IN A
18 LAB YOU PUT IN A PILL YOU GIVE TO THE PATIENT.

19 AND SO THE QUESTION IS WHAT ABOUT THE REST OF IT? IT
20 SAYS A COMPOUND OF STRUCTURAL FORMULA III OR THE OTHER THINGS.
21 WHAT DOES THIS PATENT TELL YOU ABOUT HOW THAT COMPOUND IS
22 CREATED? DOES IT TELL YOU THE BODY CREATED IT? DOES IT TELL
23 YOU THE PERSON MAKING THE PILL CREATED IT?

24 AND THE ANSWER IS, IT TELLS YOU THAT THE PERSON WHO MADE
25 THE PILL CREATED IT.

1 SO HERE'S THE EVIDENCE FOR THAT. FIRST, FORMULA III THE
2 ONE IN THE CLAIM IT'S A SUBGENUS. AND WHAT I MEAN IS THIS
3 PATENT IS IN THREE BIG PARTS. THERE'S GENUS ONE, VERY BROAD,
4 THOUSANDS OF MOLECULES WITHIN IT, UNDER FORMULA 1, GENUS 1,
5 THERE'S GENUS 2, GENUS 3, GENUS 3 IS THE ONE THEY ULTIMATELY
6 DECIDE TO CLAIM.

7 SO MY FIRST POINT TO YOU IS, JUST TO TIE UP THE EVIDENCE
8 FOR YOU, THAT FORMULA III FALLS WITHIN THE SCOPE OF FORMULA
9 ONE. ALL RIGHT.

10 SECOND, THE PATENT, THIS IS AT COLUMN 34, LINES 26 TO 30,
11 SAYS THE PHARMACEUTICAL COMPOSITIONS OF THE PRESENT INVENTION,
12 THE PHARMACEUTICAL COMPOSITION IS A PILL, COMPRISE A COMPOUND
13 OF STRUCTURAL FORMULA ONE WHICH INCLUDES THREE, AS ACTIVE
14 INGREDIENT.

15 SO THEY ARE TELLING YOU HERE IN THE PATENT, JUDGE, YOU
16 TAKE ALL OF THE POSSIBLE MOLECULES THAT ARE IN THE SCOPE OF
17 FORMULA ONE AND UNDERNEATH THAT FORMULA III, AND YOU CAN PUT
18 THOSE INTO A PHARMACEUTICAL COMPOSITION, THAT MEANS A PILL.

19 AND IT SPECIFICALLY SAYS, IT GOES ON TO SHOW YOU, ONE OF
20 THE FIVE PRIME TRIPHOSPHATES. SO THIS IS NOW SLIDE 29, WE ARE
21 LOOKING AT EXAMPLE 129. AND THIS IS THE INVENTORS SHOWING YOU
22 HOW TO MAKE IN A LABORATORY THE TRIPHOSPHATE.

23 AND THE ONLY REASON THAT I CAN THINK OF THAT YOU WOULD
24 WANT TO MAKE THE TRIPHOSPHATE IN A LABORATORY AND NOT IN YOUR
25 LIVER IS IF YOU PLAN TO DO JUST WHAT THE PATENT SAYS, WHICH IS

1 YOU CAN PUT THOSE INTO A PILL.

2 AND AGAIN, IN 2002 WHEN THIS PATENT WAS DRAFTED, IT SEEMS
3 TO BE THAT'S WHAT PEOPLE THOUGHT WAS AN ACCEPTABLE SOLUTION.
4 TODAY, WE KNOW 13 YEARS LATER, A PRODRUG IS A MUCH BETTER WAY
5 TO DO THIS.

6 BUT MY POINT IS THIS, WHEN YOU'RE TRYING TO UNDERSTAND
7 ADMINISTERING AND YOU'RE TRYING TO DETERMINE DOES
8 ADMINISTERING, EVEN THOUGH IT SAYS PRODRUG, TALK ABOUT THE
9 SEVENTH STEP DOWN IN THE LIVER OR IS IT REALLY JUST TALKING
10 ABOUT WHAT THE PERSON PUT IN THE PILL? WHY IS THE INVENTOR
11 HERE NOT SAYING HERE, THIS FIVE PRIME TRIPHOSPHATE, YOUR LIVER
12 IS GOING TO MAKE THAT, YOU DON'T NEED TO PUT THAT IN A PILL.

13 WHERE ANYWHERE IN THIS PATENT IS A DESCRIPTION OF WHAT
14 YOUR BODY DOES TO MAKE THE ACTIVE COMPOUND? IT'S NOWHERE.
15 MR. RABINOWITZ, ALL HE CAN POINT TO --

16 THE COURT: YOU CAN'T PATENT WHAT YOUR BODY DOES.

17 MR. MCCANN: YOU CAN. YOU CAN. THE CASE IS SCHERING
18 ALSO VERSUS GENEVA. AND CHIEF JUDGE RADER, FORMER CHIEF JUDGE
19 RADER SAID YOU CAN WRITE A CLAIM THAT COVERS A METABOLITE, AND
20 THEN HE SORT OF EXPLAINS YOU HOW YOU CAN DO THAT. YOU CAN DO
21 THAT.

22 WHAT I'M TELLING YOU IS I DON'T THINK THESE INVENTORS DID
23 THAT. AND THE REASON I'M SAYING THAT, THE EVIDENCE I'M
24 POINTING TO IS THE LANGUAGE THAT SHOWS EVEN THE FIVE PRIME
25 TRIPHOSPHATE, EVEN THE THING THAT'S ACTIVE, SOMEONE IS MAKING

1 IT HERE IN THE LABORATORY.

2 AND EARLIER IN THE SPECIFICATION THEY ARE SAYING YOU CAN
3 PUT ALL OF THESE DRUGS INTO A PILL. WHY WOULD YOU DO THAT IF
4 THE BODY IS GOING TO TAKE CARE OF THAT, IF THAT'S WHAT YOU ARE
5 PATENTING IS WHAT THE BODY DOES?

6 THE COURT: WELL, I MEAN, WHY WOULD YOU DO IT BECAUSE
7 YOU HAVE SOME OPTIONS. I DON'T THINK THAT -- IT'S SORT OF A
8 QUESTION THAT ANSWERS ITSELF. YOU ARE GOING TO COVER DIFFERENT
9 OPPORTUNITIES TO HAVE ACTIVE DRUG ATTACK THE VIRUS.

10 MR. MCCANN: ABSOLUTELY.

11 BUT IF YOU WANT TO COVER WHAT THE BODY DOES AS WELL,
12 SHOULDN'T THERE BE SOME DESCRIPTION SOMEWHERE OF HOW ONE OF
13 YOUR PILL COMPOUNDS IS GOING TO BECOME ACTIVE COMPOUND.

14 AND I WOULD HAVE THOUGHT THAT WHEN YOU POINT HERE TO
15 MAKING THIS FIVE PRIME TRIPHOSPHATE, YOU WOULD SAY HERE. YOUR
16 BODY IS GOING TO MAKE THIS AND THIS IS HOW AND I'M TRYING TO
17 CLAIM THAT AS WELL.

18 I GUESS WHAT I'M SAYING IS THIS, JUDGE, WHEN YOU READ THE
19 PATENT AS A WHOLE EVERYTHING IN THAT PATENTS SAYS PUT THE
20 COMPOUNDS OF THE INVENTION AND THE PRODRUGS INTO PILLS. AND
21 I'M SAYING THAT IS THE EXTENT OF THE SCOPE OF THE CLAIM.

22 AND SO ADMINISTERING IS AN ACT THAT STOPS AT THE GIVING.

23 THE COURT: YOU KNOW, I THINK BOTH OF YOU ARE -- I
24 THINK TO READ SO MUCH INTO THE WORD ADMINISTERING IS MAKING NO
25 SENSE WHEN REALLY WHAT YOU WANT TO DO IS TO HAVE CONSTRUED A

1 PRODRUG A COMPOUND OF THE INVENTION.

2 IT IS WHERE I STARTED AND WE ARE TRYING TO STUFF SO MUCH
3 MEANING INTO THE WORD ADMINISTERING THAT DOESN'T FIT.

4 TO ME IT'S WHERE I STARTED, I GUESS I HAVEN'T BEEN
5 PERSUADED. WE ARE TAKING THE WORD ADMINISTERING AND IMPORTING
6 IN ITS PLACE THE DEFINITION. THAT'S WHAT YOU ARE ASKING ME TO
7 DO, AND THEN YOU ARE ASKING ME TO CONSTRUE SOME DIFFERENT WORDS
8 IN THAT DEFINITION AS IF IT WAS IN THE CLAIM.

9 AM I WRONG ON THAT?

10 MR. MCCANN: YOU KNOW, YOUR HONOR, I WOULD BE
11 SATISFIED IF YOU FOCUSED ON THE FIRST PART THAT A PRODRUG OF A
12 COMPOUND OF THE INVENTION IS LIMITED TO THE PRODRUG THAT MERCK
13 EXPRESSLY CLAIMED.

14 IF YOUR HONOR THINKS THIS PART DOES NOT ADD DOES NOT HELP
15 THE JURY, THE PART OF IT NOT INCLUDING THE IN VIVO METABOLISM.
16 THAT'S FINE.

17 TO ME THE KEY OTHER ISSUE IN THE CASE IS THE ONE I
18 STARTED WITH WHICH IS MERCK'S INVENTION INCLUDES PRODRUGS AND
19 THEY INCLUDED THE ONES THAT THEY INVENTED IN THEIR CLAIM AND
20 THIS CLAIM IS NO BROADER THAN THAT.

21 AND SO YOU HAVE THE MECHANISM TO CONSTRUE PRODRUG A
22 COMPOUND OF THE INVENTION, AND THAT CONSTRUCTION SHOULD BE
23 LIMITED TO THOSE PRODRUGS EXPRESSLY CLAIMED.

24 THE COURT: WELL, IT FEELS LIKE A MORE DIRECT
25 RESOLUTION OF WHAT THE REAL ISSUE HERE IS. THAT'S WHY I SAID

1 WHEN I STARTED, YOU HAVE ONE CLAIM, YOU ARE TAKING A WORD, IT
2 JUST GREW ON ME, BUT YOU ARE, THIS IS YOUR KEY ARGUMENT IS THIS
3 SECOND PORTION OF YOUR PROPOSED CONSTRUCTION.

4 MR. MCCANN: TO ME, YOUR HONOR, IT'S THE HEART OF IT.

5 THE COURT: YEP. I SEE HOW IT IS. IT'S VERY CLEAR.

6 MR. MCCANN: YES. AND YOU KNOW, I CONTINUE TO
7 BELIEVE IN THE SECOND PART AS WELL. I UNDERSTAND THE COURT
8 THINKS, YOU KNOW, MAYBE THAT'S UNNECESSARY HERE.

9 THE COURT: WELL, I'M THINKING IT'S UNNECESSARY. AND
10 CLEARLY MERCK FEELS IT'S UNNECESSARY AS WELL, THEY FEEL IT
11 SHOULD BE EXCLUDED.

12 MR. MCCANN: NO, I THINK THAT YOUR HONOR, WE ARE, TO
13 ME THE HEART OF THE ISSUE IS THAT FIRST PART. AND I THINK
14 THAT --

15 THE COURT: WHAT'S THE FIRST PART?

16 MR. MCCANN: WHAT ARE THE -- WHAT PRODRUGS.

17 THE COURT: WHICH IS YOUR SECOND PART.

18 MR. MCCANN: YES.

19 FIRST PART, SECOND PART. YOU KNOW, IF WE HAD LIFE TO LIVE
20 OVER, WE WOULD REORDER THESE THINGS, YOUR HONOR, WE WOULD
21 DEFINITELY DO IT DIFFERENTLY.

22 THE COURT: WHEN I LOOK AT YOUR PROPOSED CONSTRUCTION
23 WHAT YOU ARE FOCUSING ON IS YOUR LANGUAGE, THE PHRASE "PRODRUG
24 OF A COMPOUND" MEANS THOSE PRODRUGS THAT ARE EXPRESSLY CLAIMED,
25 THAT'S WHAT YOU ARE FOCUSING.

1 MR. MCCANN: AND I WOULD BE HAPPY WITH THAT
2 CONSTRUCTION, YOUR HONOR.

3 THE COURT: OKAY.

4 MR. MCCANN: AND I THINK GIVEN THAT, I PROBABLY
5 UNLESS YOUR HONOR HAS FURTHER QUESTIONS, I SHOULD PERHAPS YIELD
6 THE FLOOR TO MR. RABINOWITZ AFTER I CLEAN UP MY DRUG COLLECTION
7 HERE.

8 THANK YOU, YOUR HONOR.

9 THE COURT: THANK YOU SO MUCH.

10 MR. RABINOWITZ, YOU GET THE LAST WORD.

11 MR. RABINOWITZ: THANK YOU, YOUR HONOR.

12 SO YOUR HONOR, I HAVE A FEW POINTS I WOULD LIKE TO MAKE,
13 BUT I WOULD FIRST LIKE TO ADDRESS ANYTHING THAT YOUR HONOR
14 FEELS WOULD --

15 THE COURT: NO, I APPRECIATE THAT. I WOULD LIKE YOU
16 TO JUST WRAP UP WITH THE POINTS YOU WOULD LIKE ME TO
17 PARTICULARLY DISREGARD THAT MR. MCCANN JUST GAVE ME OR ONES
18 THAT YOU WOULD LIKE TO COME BACK TO YOUR OWN POINTS BEING MORE
19 SALIENT.

20 MR. RABINOWITZ: I WOULD LIKE TO START WITH THE
21 POINT, I THINK I MADE IT RIGHT TOWARDS THE BEGINNING, I WOULD
22 LIKE TO DIRECT YOUR HONOR'S ATTENTION TO THE ACTUAL TEXT OF
23 CLAIM 1 OF THE '499 PATENT.

24 WHICH IS DIRECTED TO AS IT SAYS A METHOD OF TREATING
25 HEPATITIS C VIRUS INFECTION. THIS CLAIM IS NOT DIRECTED TO A

1 PRODRUG, IT DOESN'T EXPRESSLY CLAIM PRODRUG, IT EXPRESSLY
2 CLAIMS A METHOD OF TREATMENT.

3 AND IT'S ALSO NOT DIRECTED TO PHARMACEUTICAL COMPOSITIONS
4 WHICH WAS AN EXAMPLE THAT MR. MCCANN DREW FROM THE
5 SPECIFICATION, THIS IS DIRECTED TO A METHOD OF TREATMENT.

6 AND SO I THINK IT RENDERS IRRELEVANT SOME OF THE
7 ARGUMENTS THAT YOU'VE JUST HEARD BASED ON WHAT THE PATENT
8 TEACHES ABOUT, YOU KNOW, CLAIMED PHARMACEUTICAL COMPOSITIONS
9 AND CLAIMED PRODRUGS.

10 SECONDLY, I THINK THAT YOUR HONOR HIT THE NAIL ON THE
11 HEAD WHEN YOU SAID WHERE DOES THE CLAIM SAY ONLY SATE AND ONLY
12 ACYL DERIVATIVES?

13 THE ANSWER IS IT DOES NOT. IT CONTAINS THE WORD
14 ADMINISTERING WHICH IS DEFINED IN THE SPECIFICATION IN AN
15 EXPANSIVE WAY TO EXCLUDE PRODRUGS OF THE COMPOUNDS OF THE
16 INVENTION.

17 NOW -- AND THAT WOULD INCLUDE PRODRUGS OF THE SATE
18 COMPOUND IN THE INVENTION. AND IT IS POSSIBLE TO HAVE A
19 PRODRUG OF A PRODRUG, THEY ARE CALL DOUBLE PRODRUGS.

20 THE COURT: SURE.

21 MR. RABINOWITZ: I WOULD JUST LIKE TO POINT YOUR
22 ATTENTION, YOUR HONOR, TO ONE STATEMENT IN THE SPECIFICATION OF
23 THE PATENT THAT WAS I THINK POINTED OUT IN OUR BRIEF BUT WE
24 HAVEN'T DISCUSSED IT TODAY.

25 TO THE EXTENT YOU ARE BEING ASKED TO RELY ON THE EXAMPLES

1 IN THE SPECIFICATION AS LIMITING, FIRSTLY THE CASE LAW SAYS
2 THAT'S NOT RIGHT.

3 THE COURT: I UNDERSTAND.

4 MR. RABINOWITZ: JUST FOR GOOD MEASURE, COLUMN 40,
5 LINES 34 TO 36 OF THE '499 PATENT.

6 THE COURT: TELL ME THOSE LINE NUMBERS AGAIN.

7 MR. RABINOWITZ: COLUMN 40, BEGINNING AT 34 AND A
8 HALF, IT SAYS THE EXAMPLES ARE NOT INTENDED TO BE LIMITATIONS
9 ON THE SCOPE OF THE INSTANT INVENTION IN ANY WAY AND THEY
10 SHOULD NOT BE SO CONSTRUED.

11 THE COURT: YES, THAT IS IN YOUR BRIEF, I DO RECALL
12 THAT.

13 MR. RABINOWITZ: SO I QUITE FRANKLY DON'T KNOW WHAT
14 THE ATTORNEY WHO DRAFTED THIS COULD HAVE DONE MORE THAN THEY
15 ALREADY DID TO MAKE IT CRYSTAL CLEAR --

16 THE COURT: SO THIS ISN'T WHAT MR. MCCANN IS SAYING.

17 HE'S NOT SAYING THAT THE SPECIFICATION IMPOSES
18 LIMITATIONS HE CAME TO THE CLAIM. AND HE ARGUED TO ME THAT IT
19 IS THE CLAIM THAT LIMITS TO ACYL DERIVATIVES AND TO SATE AND IF
20 IT WASN'T A LIMITATION THEN WHAT'S IT DOING THERE?

21 MR. RABINOWITZ: SO IT'S BY WAY OF INCLUSION. SO
22 THOSE ARE DEFINED AS COMPOUNDS OF THE INVENTION. FOR PURPOSES
23 OF, WHOSE USE IS CLAIMED --

24 THE COURT: WELL ACYL DERIVATIVES IS NOT A COMPOUND
25 OF THE INVENTION.

1 MR. RABINOWITZ: SO I BELIEVE COMPOUNDS OF THE
2 INVENTION WOULD BE COMPOUNDS OF STRUCTURAL FORMULA III OR SALTS
3 OR ACYL DERIVATIVES THEREOF.

4 THE COURT: OKAY. WELL YOU DID TELL ME THE COMPOUND
5 OF THE INVENTION INCLUDED BOTH ACTIVE AND INACTIVE FORMS.

6 MR. RABINOWITZ: THAT'S CORRECT.

7 AND SO FAR FROM LIMITING THIS CLAIMED METHOD OF TREATMENT
8 TO THE USE OF THE COMPOUNDS THAT ARE EXPRESSLY DEFINED THERE,
9 THE CLAIM IS DIRECTED TO A METHOD OF TREATMENT THAT SAYS
10 ADMINISTERING A COMPOUND OF THE INVENTION, AND THAT'S DEFINED
11 AS PROVIDING THE COMPOUND OF THE INVENTION OR PROVIDING A
12 PRODRUG OF THE COMPOUND OF THE INVENTION.

13 SO IF THE MEANING OF ADMINISTERING AS DEFINED IN THIS
14 SPECIFICATION IS GIVEN EFFECT, THE METHOD OF TREATMENT CAN BE
15 CARRIED OUT EITHER BY PROVIDING A PILL THAT CONTAINS A COMPOUND
16 OF THE INVENTION OR BY PROVIDING A PILL THAT CONTAINS A PRODRUG
17 OF A COMPOUND OF THE INVENTION.

18 AND MR. MCCANN SAID IT'S EASY, YOU CAN MAKE IT IN A LAB,
19 YOU CAN PUT IT IN A PILL, YOU CAN GIVE IT TO THE PATIENT.
20 THAT'S TRUE OF PRODRUGS OF THESE COMPOUNDS.

21 SOFOSBUVIR IS THE EXAMPLE THAT'S AT ISSUE HERE.
22 SOFOSBUVIR IS MADE IN THE LAB, IT'S GIVEN TO PUT IN A PILL IT'S
23 GIVEN TO THE PATIENT, THE PATIENT SWALLOWS THE PILL AT MIDNIGHT
24 THE ACTIVE ADMINISTRATION HAS OCCURRED, AND THE QUESTION IS NOT
25 WHEN BUT WHAT MUST BE GIVEN, WHAT MUST BE ADMINISTERED.

1 AND WE KNOW THAT SOFOSBUVIR IS A PRODRUG OF COMPOUNDS OF
2 THE INVENTION BECAUSE THAT'S HOW IT WORKS.

3 AND THEN FINALLY I JUST WANTED TO DEAL WITH A COUPLE OF
4 THE CASES THAT WERE POINTED OUT IN MR. MCCANN'S ARGUMENT. I
5 DON'T THINK I NEED TO GO INTO THE SCHERING V. GLENMARK AND
6 HOFFMAN LA-ROCHE V. APOTEX, AS YOU POINTED OUT THEY DEALT WITH
7 ORDINARY MEANING OF ADMINISTERING, THERE WAS NO DIFFERENT
8 DEFINITION IN THE SPECIFICATION.

9 IN THE TRADING TECHNOLOGIES CASE, THE COURT APPLIED THE
10 DEFINITION IN THE SPECIFICATION BUT THE DEFINITION CROSS
11 REFERENCED OTHER PARTS OF THE SPECIFICATION. SO THE DEFINITION
12 INCORPORATED IT. THIS IS ON PAGE 1353 OF TRADING TECHNOLOGIES.

13 AND THE DEFINITION SAID THE VALUES IN THE PRICE COLUMNS
14 ARE STATIC, THAT IS, THEY DO NOT NORMALLY CHANGE POSITIONS
15 UNLESS A RECENTERING COMMAND IS RECEIVED DISCUSSED IN DETAIL
16 LATER.

17 SO FIRSTLY, THIS WASN'T ACTUALLY AN EXPRESS DEFINITION AS
18 USED HERE IN THE TERM X MEANS Y OR AS WE HAVE, THE TERM X
19 SHOULD BE UNDERSTOOD TO MEAN Y. IT WAS AN IMPLICIT DEFINITION
20 AND IT EXPRESSLY CALLED FOR REFERENCE TO OTHER PARTS OF THE
21 SPECIFICATION WHICH THE COURT DID.

22 AND IN THE ALLERGAN V. APOTEX CASE, IN THE COURT'S
23 DISCUSSION IT ACTUALLY SAID THERE WAS SOME AMBIGUITY IN THE
24 DEFINITION OF THE CLAIM.

25 THIS IS ON PAGE 958, MOST COMPELLING EVEN IF THERE MAY BE

1 SOME AMBIGUITY IN HOW THE PATENTEES DEFINED THE TERM. AND THEY
2 SAID NUMEROUS EXAMPLES IN THE PATENT WOULD BE EXCLUDED BY THE
3 DEFINITION THEY ARE REJECTED.

4 NOW IT'S ONE THING TO SAY THAT THE EXAMPLES DON'T LIMIT
5 THE CLAIM TO THE EXAMPLES, BUT THERE'S ALSO A PRINCIPLE THAT
6 SAYS THAT CLAIMS ARE PRESUMED TO COVER THE EXAMPLES BY WHICH
7 THE INVENTOR HAS EXEMPLIFIED.

8 SO IT WAS A MIXTURE OF AMBIGUITY AND THE DESIRE TO COVER
9 THE EXAMPLES THAT THE INVENTOR SAID WERE EXAMPLES OF THEIR
10 INVENTION THAT LEAD THE COURT TO ADOPT THE CONSTRUCTION IT DID.

11 I DON'T THINK EITHER OF THOSE IS APPLICABLE HERE. I
12 DON'T THINK THERE'S AMBIGUITY. I THINK IT'S VERY CLEARLY
13 EXPRESSED. AND WE ARE NOT TALKING ABOUT EXPANDING A CLAIM TO
14 COVER EXAMPLES THAT THE INVENTORS USED TO DESCRIBE WHAT THE
15 INVENTION WAS.

16 IF THERE'S NOTHING FURTHER FROM YOUR HONOR, THAT'S ALL I
17 HAVE FOR YOU.

18 THE COURT: THANK YOU.

19 MR. MCCANN: WAS THAT TOTALLY THE LAST WORD,
20 YOUR HONOR?

21 THE COURT: IF THERE'S SOMETHING THAT YOU THINK WOULD
22 BE OF HELP TO ME.

23 MR. MCCANN: I JUST, REALLY ONE THING.

24 MR. RABINOWITZ, HE TWICE SAID THAT THIS IS A METHOD OF
25 TREATMENT CLAIM. AND I JUST WANT TO SAY I DON'T SEE HOW THAT

1 MAKES THE LEAST BIT OF DIFFERENCE AS TO WHETHER YOU CLAIM
2 PARTICULAR PRODRUGS BUT THEN LATER SAY THAT I ACTUALLY MEANT
3 ALL THE OTHER ONES AS WELL.

4 I MEAN, THIS IS WHAT YOU USE THEM FOR IS TO TREAT PEOPLE
5 WITH. SO THE FACT OF THE CLAIM THIS PARTICULAR CLAIM THE
6 STRUCTURE IS A METHOD OF TREATMENT I THINK THAT HAS NOTHING TO
7 DO WITH THE ARGUMENT I'M MAKING FOR SURE.

8 THE COURT: WELL, I THINK THAT YOU HAVE NARROWED THE
9 ISSUE FOR ME SO THAT I CAN PROVIDE A CONSTRUCTION THAT WILL
10 MOVE US TO THE NEXT POINT.

11 REMIND ME, BECAUSE I DON'T HAVE MY ENTIRE FILE HERE, I
12 PRESUME WE HAVE NO FURTHER DATES BEYOND CLAIMS CONSTRUCTION
13 THAT HAVE BEEN STATED IN THE OR HAVE WE?

14 MR. MCCANN: THERE'S A SUBSTANTIAL NUMBER,
15 YOUR HONOR.

16 THERE'S A TRIAL DATE AND THERE'S, I BELIEVE, A
17 DISPOSITIVE MOTION DATE. THERE IS A FAIRLY GOOD CASE SCHEDULE
18 IN PLACE.

19 THE COURT: IS THERE ENOUGH TIME -- SOMETIMES WE WAIT
20 UNTIL CLAIMS CONSTRUCTION TO SPELL OUT THOSE DATES. SO IN YOUR
21 CASE, I'VE ALREADY GIVEN YOU THOSE DATES?

22 MR. MCCANN: YES, YOUR HONOR.

23 THE COURT: I DO IT DIFFERENTLY IN THE CASES.

24 SO IF MY, I DON'T KNOW HOW LONG THIS WILL TAKE, YOU KNOW
25 IT'S CERTAINLY NOT AS DIFFICULT AS CONSTRUING TEN CLAIMS OVER 4

1 OR 5 PATENTS BUT THIS IS A KEY ISSUE IN THE CASE.

2 SHOULD MY ORDER COME OUT AND THAT WOULD AFFECT THE REST
3 OF THE SCHEDULE, PLEASE DON'T HESITATE TO LET ME KNOW AT THE
4 EARLIEST POSSIBLE MOMENT SO THAT WE CAN LOOK AT THAT SCHEDULE
5 AND MAKE SURE THAT IT WORKS.

6 WELL, THANK YOU ALL VERY MUCH. I GREATLY APPRECIATE THE
7 EXTRAORDINARY QUALITY OF THE PRESENTATIONS AND THE CARE IN
8 WHICH YOU'VE TAKEN IN EDUCATING THE COURT. IT'S ALWAYS
9 APPRECIATED.

10 I THINK WE'RE DONE.

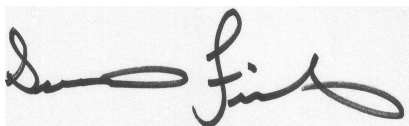
11 MR. MCCANN: THANK YOU, YOUR HONOR.

12 (WHEREUPON, THE PROCEEDINGS IN THIS MATTER WERE CONCLUDED.)
13
14
15
16
17
18
19
20
21
22
23
24
25

CERTIFICATE OF REPORTER

I, THE UNDERSIGNED OFFICIAL COURT
REPORTER OF THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH
FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY
CERTIFY:

THAT THE FOREGOING TRANSCRIPT,
CERTIFICATE INCLUSIVE, CONSTITUTES A TRUE, FULL AND
CORRECT TRANSCRIPT OF MY SHORTHAND NOTES TAKEN AS
SUCH OFFICIAL COURT REPORTER OF THE PROCEEDINGS
HEREINBEFORE ENTITLED AND REDUCED BY COMPUTER-AIDED
TRANSCRIPTION TO THE BEST OF MY ABILITY.

A handwritten signature in black ink, appearing to read "Summer A. Fisher", is written over a light gray rectangular background.

SUMMER A. FISHER, CSR, CRR
CERTIFICATE NUMBER 13185

DATED: 4/3/15